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# March 2007 Final Report Puget Sound Infectious Disease Tracking System Award Number: W81XWH – 04-1-0418

#### **Introduction:**

This study looked at the operational efforts required to develop advanced tools for public health surveillance and disaster management and developed evidence-based knowledge to help shape these efforts. The approach was to rapidly leverage existing, deployed computerized public health data collection systems in the Puget Sound region, and build several new components to create a laboratory for the "field study" in this proposal. The project built a system of sentinel sites that assisted us to answer the following categories (themes) of questions: **feasibility** – feasibility of automated and manual reporting under a variety of settings and implementation models; **relative utility** – relative utility of the data gathering through these techniques (evaluating each technique alone and the synergism from using both techniques in the same population for surveillance and detection); **technical and policy approaches** – developed technical and policy approaches to cooperation including the implication of bi-directional data exchange between civilian and military public health surveillance systems.

# <u>Statement of Work</u>: Puget Sound Infections Disease Tracking System/ renamed by workgroup to Outbreak Detection Information Network (ODIN)

Detection finormation Network (ODIN)					
Task 1	Status – Research Accomplishments				
<b>Task 1:</b> Community Initiative – Use a community based approach to assist in gathering requirements for data collection and data sharing across jurisdictions. (Months 1-6)	Completed Fall 2003: Received letters of support from Seattle & King County Public Health, Kitsap County Health District, Washington State Department of Health, Tacoma-Pierce County Department of Health, and Department of the Army – Madigan Army Medical Center. All letters indicated support for a broadbased community approach to assist in determining requirements for data collection and data sharing across respective jurisdictions.				
Task 1 a. Create an executive management team of key stakeholders including investigators, key participants and administrative resources.(Month 1)	Completed: Initial management team created in Fall 2003; Reorganized management team became effective August 2006: The initial management team was identified during the first month of the Project. (See Appendix A for original names, of titles and organizational affiliations.) As was noted in previous reports, during the course of these meetings, several technical and policy issues were identified. In order to better address the issues, a chartering process was undertaken. At the conclusion of the chartering process in December 2006, the management team identified is as follows: Washington State Department of Health: Jude Van Buren, Dr., PH, Assistant Secretary of Health; Kitsap County Department of Health: Scott Lindquist, MD, Health Officer; Tacoma-Pierce County Health Department: Vic Harris, PhD, Deputy Director; Foundation for Health Care Quality: Dr. Peter Dunbar, PI, Andy Fallat, CEO, FHCQ; and				

	Paladin Data Systems: Gary Macy, Chief Technical Officer (See Appendix B for complete copy of ODIN Health Data Surveillance and Analysis Toolkit Project Charter)
<b>Task 1 b.</b> Identify potential participant sites to include the principal emergency departments in the participating counties. These sites will be representative of the "Sea-Tac" corridor and will include facilities contiguous to the Ft. Lewis, McChord A.F.B, Bremerton Naval Yard, Everett Home Port, and the NAS Whidbey Island. (Month 1)	Completed August 2006: Preliminary sites were identified in Fall 2003; at the conclusion of the chartering process, participating organizations/ sites include: Washington Department of Health, Tacoma-Pierce County Health Department, and Kitsap County Health District. These jurisdictions include principle emergency departments sites in participating counties and include military facilities at Fort Lewis, Bremerton Naval Base.
Task 1 c. Implement a joint application development process using identified subject matter experts to identify and document data and system requirements for the web-based data collection.	<u>Completed</u> : A joint application development process was implemented within the initial 3 months of the project. There were unanticipated difficulties in directly obtaining the time required from the local public health officials to identify requirements. In addition different local health jurisdictions used different methodologies for syndromic surveillance, and obtaining agreement of requirements would have been challenging.
	We found that we could successfully obtain good requirements without direct access to end users for requirement elicitation by the development team by using a super-user approach ([1]). The super-user approach involves using a surrogate user in place of actual end users when end users are unavailable for direct consultation. For this approach to work the surrogate user must have domain knowledge and have knowledge of how end users operate.
	The super-user obtained the knowledge needed to generate good requirements through  1. Interactions with the local health jurisdictions

- participating in the project,
- 2. Interactions with project participants at the University of Washington School of Public Health.
- 3. Conducting a review of and developing expertise in current syndromic surveillance systems (including CDC's BioSense project, Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE), Realtime Outbreak and Disease Surveillance (RODS), Over-the-Counter drugs and other items (OTC), and Early Aberration Reporting System (EARS), using access provided by the local health jurisdictions,
- 4. Systematic review of the syndromic surveillance literature.
- 5. Attending and presenting at academic and industry conferences

The super user interacted with subject matter experts by making himself available as a PhD Biostatistician that the local health jurisdictions could use as a resource. This enabled the super-user to observe what challenges were facing the end users.

We found that the joint application process worked well in terms of anticipating technical requirements and operational patterns. The need for involvement with the stakeholder organizations by the "super user" lessoned as more the requirements of the system are understood. However, it should be noted, without direct involvement of the stakeholder organizations it was difficult to prioritize development.

**Appendix** C lists the requirements developed from the charter process together with the status of these requirements in the development process of ODIN at the start of the charter process.

Identify all necessary mechanisms to ensure the security and privacy of proposed data collection is consistent with HIPAA requirements. (Months 1-3)

The data access model for ODIN was designed to meet security and privacy issues. No "limited data set" data is stored within ODIN. Access to encounter level details is subject to authorization by the jurisdiction that the data was collected in. Access to aggregate data can be given to a user while withholding access to encounter level data.

**Task 1 d.** Draft detailed requirement documentation including logical data models, use cases, activity diagrams and functional specifications, and review with all participants, stakeholders and potential users. This would include the reconciliation of requirements with pertinent data, privacy and other standards, including National Health Information Infrastructure (NHII) and National Electronic Disease Surveillance System (NEDSS).

We found that these standards did not impact core system development. Outside interfaces within ODIN were designed to be compatible with other systems.

The ODIN system was designed to be hosted by public health organizations that have in place the necessary privacy and security framework for access to sensitive data. The system is designed to reside behind the host organizations firewall.

Logical data models were crafted by the IT contractor. Requirements documents were generated and consisted of functional specifications (including screen shots) and use case (activity) diagrams.

Prototypes of the requirements were implemented in monthly sprints, and requirements modified based on test usage of the designs and technical considerations. Due to the restrictions on direct access to potential users (see 1c), in progress requirements were not shared with potential users. Instead demonstrations of the phase I prototype were used to gain user feedback. Feedback from these demonstrations showed that the requirements generated through the super-user approach matched the needs of the local health jurisdictions.

Create prototype models to test the functional acceptances and review the prototype models or the proposed system with all participants, then re-craft requirements based on prototype review. (Months 3-5)

Two prototypes for ODIN was created (called the phase I prototype and the phase II prototype.). We found that both prototypes had the technical capacity to host at least 2 years worth of encounter data for the state of Washington, roughly 1-2 million patient encounters. Two years worth of encounter data for the State of Washington was simulated and loaded into the prototypes with no impact on performance.

Demonstrations were given to each local health jurisdiction, the Washington State Department of Health and the army, and feedback in terms of changes and additional requirements collected. We found that the prototypes contained sufficient functionality to meet the basic needs of the health jurisdictions.

The prototype was also shown at the (Puerto Rico Conference), but could not be demonstrated 'live' due to technical limitations at the conference site. [2] See appendix D

#### **Task 2 – Case Reporting**

#### **Status- Research Accomplishments**

**Task 2** – Case Reporting – Rapidly develop a web-based case reporting system for syndromic clinical data, and implement that system in a variety of healthcare organizations throughout a four County area in Western Washington region. (Months 5-24)

See Appendix E dated 12/23/03 documenting that the Statement of Work remains an accurate description of the proposal. The four Sub-tasks under Task 2 remain relevant except that they will be applied to other collection methods consistent with ESSENCE.

Public Health leaders, both local and national, were found to be highly skeptical of a web-based system approach. AIBS Peer Review to USAMRMC identified this component of the study as a weakness. Public health leadership recommended a more reliable and affordable approach to developing an accurate information system for syndromic surveillance. Public health officials requested the project focus on developing techniques with reasonable expectations for the long-term value. As reported in March 2005, based on immediate feedback on this approach, the web-based case reporting system is not being pursued. This

decision does not require a change in the Statement of Work. We found that a web based case reporting system was strongly indicated against by the project participants. During the run-up to the start of the grant a shift away from case reporting systems occurred. While there are documented positive benefits to a case reporting system (develop relationships with hospital staff, easy to initiate, detailed information obtainable) and it has been successfully used on a drop in basis. [3] However, it is widely recognized as labor intensive and difficult to maintain, and experience has shown it to be not a sustainable form of surveillance [4] Task 2 a. Develop and review technical specifications to support See 1c. detailed requirements identified by participants, stakeholders and users. Develop plan for unit and acceptability testing. Develop use cases from functional specifications to guide development and testing (Months 5-7) Develop use cases from functional specifications to We found that the rapid prototyping approach worked well in the guide development and testing (Months 5-7) development environment. Logical data models were crafted, requirements documents were generated and consisted of functional specifications (including screen shots) and use case (activity) diagrams. Prototypes of the requirements were implemented in monthly sprints, and requirements modified based on test usage of the designs and technical considerations. Due to the restrictions on direct access to potential users, in progress requirements were not shared with potential users. Instead demonstrations of the phase I and phase II prototypes were used to gain user feedback.

Feedback from these demonstrations showed that the requirements generated through the super-user approach matched the needs of the local health jurisdictions.

Testing system using simulated data: A large data set was simulated and used to test the functionality and capacity of the system. The data consisted of simulated data over a 2 year period for the State of Washington (a total of 834564 encounters). The simulation was designed to provide data with similar characteristics to actual syndromic surveillance data, and included nuances of missing data, subtle and gross errors in data, simulated outbreaks and other data anomalies. The simulated data demonstrated the capacity of ODIN system to handle data of at least twice the anticipated final data size, and successfully demonstrated the implementation of the functionality. In addition, it provided a convenient test bed for iterative requirements development.

Findings from the requirements directed the technical specifications. Key findings from the requirements process include:

- 1. Algorithms should not be fixed, as different preferences and evolving development of algorithms, flexibility of algorithm implementation is key.
- 2. Geographic units should be flexible and multilevel. For example, a large proportion of Kitsap County is covered by a single zip code, so that zip codes do not provide sufficient geographic detail for spatial analyses in this county. However King County is covered by over 100 zip codes, and zip codes provide too much detail for many purposes.

	<ul> <li>3. A multi-tiered security model is needed for implementation of a system across multiple jurisdictions.</li> <li>4. Multiple usage pathways are required to support the different business processes that the local health jurisdictions have.</li> <li>5. The interpretation of data and alerts depends on local knowledge about the nature of the data.</li> </ul>
Task 2 b. Perform assessments of workflow and technical capacity at participating sites to select an option, and then document implementation plan, both to assure implementation of success as well as to characterize variations in operational patterns, personal technical capacity and other key implementation issues. (Months 7-9)	Assessment of workflow and technical capacity at the participating sites was completed. Based on assessment and input from sites, the system is being designed to support a number of tools as well as allow the user to develop their own tools and extensions. The system has the functions listed below:  1. Securely encrypt, transmit, stage, process, store and present data using data warehousing industry's best practices  2. Plug-in capability for interchangeable tools or methods to group (unstructured text chief complaint data into syndromic classes  3. Plug-in capability for interchangeable tools or methods to analyze the data and detect anomalies and patterns  4. Present data analysis result summaries using table, graph and geo-spatial map visualizations and drill down capability.  5. Automatically trigger anomaly alerts based on detection findings and queue notification messages for distribution.  A key finding is that each of the local health jurisdictions has different capabilities for surveillance and different work flow processes.

	We found that the super-user approach allowed us to develop an adaptable system to meet the requirements of the different work flow processes. We found during demonstrations of the phase I and phase II prototypes to potential end users that almost all current and future needs had been incorporated, or were planned to be incorporated, into the ODIN system.  We found that there was a need for more in depth research into the work flow processes within local health jurisdictions, and arranged for this work to be carried out by the University of Washington through the subcontract. <i>The results of this research are pending</i> .
<b>Task 2 c.</b> Implement the case reporting application, and perform unit and acceptance testing on both the web application and the central server. (Months 8-11)	Answered in 1c.
Task 2 d. Implement the system at participating sites, and provide ongoing follow-up assessment, support and documentation of implementation issues through the use of third party web-deployed issues tracking tools, and through contract reporting (Months 11-24)	Completed December 2006: As reported earlier, implementation of system prototype testing at participating sites was originally planned for June/July 2005. Due to issues raised regarding control of data, control of the project and related liability issues of forprofit company as a contactor for software development and concerns regarding access to protected health information, there was a delay in testing the at participating sites. As part of the decision making associated with the Chartering process, participates agreed to test the system at their respective sites. As of March 2007 the following sites are participating in the pilot implementation. Washington State Department of Health, Kitsap County Department of Health, and Tacoma-Pierce County Health Department.

Task 3 – Automated Data Collection/Integration	
Task 3 – Automated Data Collection/Integration – Data will be collected from the sentinel healthcare organizations in all participating counties, with the direct reporting of data to the local health jurisdictions. Integrate the data from the web-based case reporting system, the automated data collection system, and the military's public health surveillance system, the support appropriate access by both military and civilian health authorities.	As noted specificat methodol Integration rules based data in a second specific rules based at a in a second specific rule rule rules based at a second specific rule rules based at a second specific rule rules based at a second specific rule rule rule rule rule rule rule rule
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#### **Status- Research Accomplishments**

As noted in the March 2005 report, the system design specifications and scope documents identify the approach and methodology to be used for Automated Data Collection and Integration. The system was designed to incorporate a "smart" rules based data collection engine which is capable if collecting data in a variety of formats from a wide range of organizations.

We found that it was not practical to collect 'live' data while system development was in progress. In particular we found that due to concerns by public health jurisdictions about jeopardizing their relationships with local hospitals, they were not willing to let live data be put into a system under development and hosted outside of the jurisdictions.

We found that we could use simulated data developed according to specifications provided by the local health jurisdictions and based on published work for testing and development purposes for all parts of the system except for the data import processes.

**Task 3 a.** In concert with the Community Initiative, develop technical agreements with the IT groups of sentinel sites healthcare organizations with all counties, to cover data elements, coding, security, and service-level agreements. Develop similar agreements with Madigan for centralized exchange of ESSENCE II or similar regional military data. (Months 1-12)

Completed December 2006: The Charter is the formal reference for shared assumptions intended to guide and define the ODIN project. As noted in the Charter, State of Washington Department of Health agreed to "host" the ODIN technical system, perform project management activities and coordinate all activities with the two local health jurisdictions Kitsap County Health District and Tacoma-Pierce County Health Department including completing agreements to cover data elements, coding, security and service level agreements as required. The overall approach is

to compare two syndromic surveillance software applications in their ability to gather, process and provide disease incidence data on which to base public health response decisions. The emergency room facilities within Kitsap County and Tacoma-Pierce County currently report disease data in a automated surveillance application (ESSENCE), that data will be copied and sent through the ODIN process algorithms and made available at the password protected web-based portal for use by the county public health systems. The data from the two systems will be used to inform the public health staff. Additional funding (\$3.6 M) was requested to continue the technical development, develop and validate additional statistical techniques, train staff, and continue to extend the technical system capabilities.

An evaluation will be conducted through December 2007 to provide feedback on the advantages and challenges of both systems. (See Appendix F for Agreement between Foundation for Health Care Quality and State of Washington Department of Health)

**Task 3 b.** Extend our present server architecture to accommodate required scaling, add additional site-specific normalizations, and extend query structure to include multi-jurisdictional data access. (Months 1-6)

The system design specification is scalable both in capacity and capability. Based on industry standard data management products, the system uses self-defining data structures throughout its design, allowing for future expansion and addition of data sources without requiring a programmatic change. Access to the information in the system is controlled by a robust security protocol which provides granular access management and system journaling.

We found that there were no technical difficulties in implementing the scalability; the system was designed from the bottom up to be scalable and cover multiple jurisdictional needs.

**Task 3 c.** Implement automated data collection, easing the present 3-tier, HIPAA compliant data model at the sentinel sites. We anticipate being able to implement at multiple site in each participating county over this period. (Months 3-21)

(Analysis and recommendation of HIPAA application provided by John R. Christiansen, Christiansen IT Law, a law firm specializing in technology related services)

Scope of data available for contribution to ODIN: HIPAA prohibits disclosure of Protected Health Information for most public health purposes, unless individual authorization is obtained. Obtaining such authorization may be difficult or sometimes impossible. However, HIPAA expressly does permit disclosure of "Limited Data Sets" for public health purposes without such authorization. Limited Data Sets appear to provide sufficient information for ODIN purposes. Authority to use data processing vendors to provide ODIN data: Many hospitals rely upon data processing services vendors to store and manage their Protected Health Information. However, HIPAA requires Covered Entities (including hospitals) to limit the uses and disclosures such vendors may make of their Protected Health Information. Model contract provisions authorizing vendors to create and disclose Limited Data Sets on behalf of hospitals for public health purposes, including ODIN, have been developed and found acceptable to both a major data processing services vendor and a number of hospitals. (See Attachment D)

The system has been implemented at the participating local health jurisdictions and health care organizations.

We found that considerable organizational challenges around data sharing along with competing efforts prevented implementation of the ODIN system at sites until these issues are resolved.

Currently all planned surveillance capabilities within ODIN make use of limited data sets. There are no direct legal impediments to

	local public health jurisdictions receiving limited data set data from hospitals. [5]  There is however the potential for hospitals to be cautious about
	sharing limited data set information with public health jurisdictions due to perceptions of HIPAA related concerns [6]
<b>Task 3 d.</b> Develop and implement support for bi-directional exchange of data with military systems, working at either the regional level with Information Technology staff at Madigan Army Medical Center, or at the national level with the ESSENCE staff. (Months 6-12)	There has been an ongoing communication with key points of contacts with military systems since the beginning of the ODIN project.  Julie Pavlin, M.D., M.P.H., Walter Reed Army Institute of Research initially served on the Steering Committee. After the ESSENCE project was transferred to Health Affairs, Col Kenneth L Cox, Director, Force Health Readiness, Health Affairs replaced
	Dr. Peter Dunbar, PI and Linda Lekness participated in a conference call with Col. Cox on 2/3/05. Col. Cox expressed interest and support for the project. Additional communication with Col Kenneth Cox occurred on 4/13/05; 5/05; 7/31/05 and on 8/25/05 Dr. Dave Ross, Consultant to the ODIN project, completed a phone interview with Col Cox as part of Dr. Ross's effort to complete a needs assessment of users of the ODIN system. On 1/25/06 Dr. Bud Nicola and Laura Ripp completed a phone interview with Col Cox as part of the charter development process. As "lessons learned" become available from other similar projects, Col Cox has offered to provide that information to the ODIN project.  Additional coordination with military systems include: Dr. Peter Dunbar met with Lieutenant Colonel Andrew Wiesen, MD, PhD, Clinical Assistant Professor, Madigan Army Medical Center,

Wiesen stated that since Madigan was already reporting data to ESSENCE and that once the project had reached the appropriate milestones he would be interested in working out additional details. On May 13, 2005 Lt. Col Andrew Wiesen participated in a presentation of the ESSENCE system to ODIN stakeholders including Dr. Jude Van Buren, Assistant Secretary, Washington State Department of Health, Dr. Ian Painter, Biostatistician and Linda Lekness. Lt Col Wiesen was provided a brief status report at this time.

As noted in Task 1a status, written monthly progress reports have been submitted to the military points of contacts for the ODIN project.

Finally the project team has continued to stay in touch with professionals across the country working on similar projects. For example, BioDefend, a project between the University of South Florida's Center for Biological Defense and Datashpere, LLC have developed a system for conducting bioterrorism and infectious disease surveillance. The BioNet project was also contacted but working with this project was not feasible due to the work being classified. This project is also working toward bi-directional exchange of data with military systems, working at either the regional level or national level in coordination with Col Ken Cox. As of March 2007, bi-directional exchange of data has not been implemented. This effort will continue to be pursued with additional funding received.

**Task 3 e.** Continue to improve and maintain centralized integration server, and continue to improve and maintain secure data transmission using both accepted and evolving standards for security and message protocols. (Months 12-24.)

We found that establishing the system in the Department of Health and the commencement of data flow into the system has renewed interest by local public health agencies in investigating the inclusion of alternative data sources for surveillance purposes.

Task 4 – Utility Assessment/Detection and Visualization	Status- Research Accomplishments
Task 4 – Assess the individual and combined utility of web-based case reporting and automated data collection on the same populations through application of existing algorithms and visualizations. (Month 1-24)	AIBS Peer Review to USAMRMC identified the component of assessing web based reporting as a weakness in the project. Based on immediate feedback on this approach, the web-based case reporting system is not being pursued. See Appendix dated 12/23/03 documenting that the Statement of Work remains an accurate description of the proposal. The sub-tasks under Task 4 remain relevant as reported below.
<b>Task 4 a.</b> Gather algorithms inclusion criteria: use in a bioterrorism or epidemic detection system.	Through a comprehensive review of the issues in algorithm development and implementation we found that the algorithm development field for syndromic surveillance had not fully matured, and that no consensus on best practice algorithms existed, and that considerable development effort was going into producing better algorithms. Accordingly we design the ODIN system to allow multiple algorithms to be included.
Task 4 b) Test/evaluate the performance of the above approaches against set historical outbreaks and novel outbreaks.	We also found that there are considerable uncertainties about whether the performance of an algorithm (or syndrome coder) on one set of data will reflect the actual performance on a different set of data, that is to say, there may be considerable local variability in performance. The University of Washington through its subcontract developed a system using a web based services model that enables analysis of algorithm performance to be conducted over the web against standard datasets and outbreak models without the technical implementation knowledge typically needed to conduct these simulations. Given the flexibility requirements of algorithm implementation within a multijurisdictional syndromic surveillance system, and the requirement that local knowledge of data patterns is required that we found (see section 2a), a web based services model that allows the analysis of algorithm performance against local data is important.

	One of us (Dr Painter) also was involved in a large simulation study to systematically look at the performance characteristics of several commonly use algorithms within a large public health jurisdiction [7].
Task 5 – Ethnographic Analysis	Status- Research Accomplishments
Task 5 – Ethnographic Analysis – Appraise the value of syndromic clinical data to decision makers in public health and disaster management by conducting structured, retrospective assessments of the personnel involved with three recent events: the ongoing smallpox vaccination program, the SARS outbreak, and the 2003 Seattle TOPOFF exercise. (Months 1-24)	As part of the condition of participation in this project by Public Health, ethnographic analysis was not pursed.
Task 5 a. Dissemination of Results – All investigators will seek to present intermediate and final results through conference presentation and peer review publication. This is anticipated to begin in month 6, based on extension of prior work, and extend past the end of the contact. (Months 6-36)	Results dissemination through posters and presentations. See reportable outcomes.
Task 5 b. Project Reporting – All investigators will assist the Principal Investigator in providing reporting as required to satisfy contact terms (Months 1-24)	

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#### **Key Research Accomplishments:**

- We developed a formal reference document (charter) that enabled cross-jurisdictional cooperation in organizing a multiiurisdictional surveillance system (task 1):
  - We found that there are considerable organizational and political barriers to developing and employing cross-jurisdictional surveillance systems.
  - o We found that these organizational and political barriers could be successfully navigated a formal chartering process.
  - We developed a final signed charter document and on the basis of this document installed a state of the art surveillance system at the Washington State Department of Health.

- We designed, developed and installed a state of the art syndromic surveillance system that accepts multiple data sources and provides a region-wide view of information in the system (tasks 2, 3 and 4):
  - We found that a rapid application development approach together with a super-user could successfully develop such a system without direct access to end users.
  - We found that there were no technical difficulties in developing the system, in part due to the implementation of a solid and flexible system and database architecture.
  - o We found that advanced visualization tools could be delivered over the web using a web browser as client.
  - We developed several advanced visualization tools designed to overcome screen real-estate limitations when displaying multi-level data.
  - o We found that in general the development of appropriate analytical tools is in an immature state, and novel tools with improved performance are expected to emerge. For this reason we focused on building in flexibility in the selection and implementation of analytical tools into the system.
- ODIN stakeholder collaboration with the University of Washington School of Public Health and Community Medicine actively supported the development of the Center for Excellence in Public Health Informatics at the University of Washington (tasks 2b)
  - o The Centers for Disease Control and Prevention awarded a grant in the amount of \$3.8 million to the University of Washington School of Public Health and Community Medicine to support the development of a Center for Excellence in Public Health.
  - o This center will continue to advance the science of syndromic surveillance and public health informatics in general, long after the ODIN project is completed.
  - o The center will continue to build on the collaboration between and among the Department of Defense and the civilian Public Health community.

**Reportable Outcomes:** (and associated tasks)

#### **Posters and Presentations:**

• Bliss D, Karras BT. "Interactive 3D Visualization of Public Health Geographic Data Using Google Earth" [computer demonstration] 4th Public Health Information Network (PHIN) Stakeholders Conference, Atlanta, GA. 2006 Sept (task 4)

- Boyce RD, Karras BT, Lober WB. Pre-processing to improve the classification of chief complaint data. [paper/oral presentation] Syndromic Surveillance Conference, Seattle, WA. 2005 Sept (*task 4*)
- Doctor J, Baseman J, Karras BT, Lober WB. "Multi-attribute Utility Theory for Prioritizing Data Elements for Surveillance using Regional Health Information Organization Data" [poster] (task 3a)
- Dunbar, PJ, IS Painter, L Lekness (2006) Puget Sound Infectious Disease Tracking System. Poster and demonstration presented at the Department of Defense Military Health Research Forum, Puerto Rico, May 2006. (*all tasks*)
- Karras BT, "Detecting emerging diseases" [Invited Plenary Speaker], Sichuan University, Chengdu, China 2006 Sept (*all tasks*)
- Karras BT, Detmer D, The Convergence of Public Health and Biomedical/Health Informatics, 4th Public Health Information Network (PHIN) Stakeholders Conference, Atlanta, GA. 2006 Sep (*task 3*)
- Karras BT, "Development and Utilization of Competencies for Public Health Informatics" [Panel organizer and presenter] 4th Public Health Information Network (PHIN) Stakeholders Conference, Atlanta, GA. 2006 Sept (*all tasks*)
- Lober WB, Mandl K, Mostashari F, Overhage JM, Wagner M, Modern Health Surveillance, [Panel Organizer/Presenter] AMIA Symposium, Washington DC, Nov 2005. (*all tasks*)
- Lober WB, Oberle M, Mandl K, Platt R, Making Regional and National Health Information Exchanges Work for Public Health: The Vision of the CDC Centers of Excellence in Public Health Informatics, [Panel Presentation] 4th Public Health Information Network (PHIN) Stakeholders Conference. Atlanta, GA. 2006 Sept. (all tasks)
- Painter I, A Harvey, K. Peterson, K. Welling, K. Taylor, P.T. Tran (2006) Some Interactive Data Exploration Tools for Syndromic Surveillance. Poster presented at the Syndromic Surveillance conference Baltimore 2006. (*task 4*)
- Painter I, K Sebestyen, T Lumley (2005) Effects of coder misclassification on outbreak detection. Poster presented at the Syndromic Surveillance conference Seattle 2005. (task 4b)
- Wagner S, Karras BT. Quality Analysis of Syndromic Surveillance Data [poster presentation] 4th Public Health Information Network (PHIN) Stakeholders Conference. Atlanta, GA. 2006 Sept (*task 4*)

#### Peer reviewed publications:

- Karras BT, Bliss D, Lober WB, Horn S, Lindquist S, Information Collection SSIC-GeoCodes for urban to rural mixed environments, *Advances in Disease Surveillance 2006;1:38*
- Jackson, M.L., A. Baer, I. Painter and J. Duchin (2007) A simulation study comparing aberration detection algorithms for syndromic surveillance. BMC Medical Informatics and Decision Making 2007, 7:6 ([7])
- Lober WB, Drozd D, Lumley T, Sebestyen K, An Open Source Web Services Toolkit for Event Detection Algorithms, *Advances in Disease Surveillance 2006;1:78*
- Lumley T, Sebestyen K, Lober WB, Painter I. An open source environment for the statistical evaluation of outbreak detection methods. AMIA Annu Symp Proc. 2005;:1037. (*task 4*)
- Revere D, Madhavan A, Kimball AM, Turner A, Bugni P, Fuller S. myPublicHealth: Research in Public Health Knowledge Management to Support Evidence-Based Practice. In Proceedings of the CDC's Public Health Information Network (PHIN) Conference, Sept 2006. Atlanta GA. (all tasks)

#### **Associated Activities:**

- (2004) Paladin Data Systems received a \$1.8 million contract from the US Army Space and Missile Defense Command. This funding is being used to conduct additional research and expand the PSIDTS. (*task 3*)
- (2006)- Paladin Data Systems received notice of award for \$1,882,321 funding request for the expansion of technical system availability; development and validation of additional statistical techniques to improve the effectiveness of technical system in support of community health objectives and force protection/force readiness functionality; implementation for, and training of additional local health jurisdictions and military commands on effective use of the system; and extend the health system interconnective networking capabilities developed for the system in support of the National Health Information Infrastructure and National Bio-surveillance Integration System efforts. (all tasks)

- ODIN project activities have substantially strengthened the University of Washington's expertise in public health informatics, which has lead to further extramural funding in support of education, research, and regional public health practice: (all tasks)
  - o Center for Excellence in Public Health Informatics
  - o Public Health Informatics Fellowship Program in collaboration with the University of Washington program in Biomedical and Health Informatics (RWJ/NLM)
  - o Public Health Reporting of Electronic Data (PHRED) research support (WA Department of Health)
  - o Poison Control Center surveillance support
  - o Fogerty Grant for International Public Health Informatics

#### **Conclusions**

The difficulties in the development of public health informatics systems that impact multiple jurisdictions are primarily organizational and political in nature. Progress on both the technical development of a system and the organizational development can proceed in parallel if sufficient flexibility is built into the technical architecture. Further research into public health informatics, especially in regard to cross jurisdictional issues, would be beneficial.

#### **Puget Sound Infectious Disease Tracking System**

Executive Management Team of Key Stakeholders including Investigators, Key Participants and Administrative Resources:

Dr. Peter Dunbar, Principal Investigator, Puget Sound Infectious Disease Tracking System

Dr. Mark W. Oberle Professor and Associate Dean, School of Public Health, University of Washington

Gary Macy Executive Vice President/CTO, Paladin Data Systems

Andy Fallat CEO, Foundation for Health Care Quality

Dr. Ian Painter, Biostatistician, Puget Sound Infectious Disease Tracking System

Jerry Tonkavich Consultant, OTB Solutions Group Seattle, Washington

Nigel Turner, MPH, RS Epidemiologist, Pierce County

Michael C. Davisson, State of Washington Department of Health

Linda Lekness, MBA, MSN, RN, Executive Director, Puget Sound Infectious Disease Tracking System

Jude Van Buren, Dr. PH, MPH, RN, RS Assistant Secretary, Epidemiology, Health Statistics and Public Health Labs, State of Washington Department of Health

Dr. Chris Leininger, Chief Information Officer, Swedish Hospital Seattle, Washington

Dr. Jeff Duchin Chief Epidemiologist, Seattle/King County Health Department

Dr. Scott Lindquist, MD, MPH Chief Epidemiologist, Seattle/King County Health Department

# ODIN Health Data Surveillance and Analysis Toolkit Washington State Pilot Implementation

### **Project Charter**

Version 4.0

Final: January 4, 2007

Report Type	Project Name		
Project Charter	ODIN Health Data Surveillance and Analysis Toolkit		

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#### SIGNATURE PAGE

## Project Charter for

### **ODIN Health Data Surveillance and Analysis Toolkit**

The purpose of this Project Charter is to document and support the operational foundation of the ODIN Health Data Surveillance and Analysis Toolkit. This Project Charter describes the intent, scope, organization, and the general proposed plan for Toolkit development, testing, pilot implementation and evaluation as approved by the following members of the ODIN Steering Committee:

Signature	Title	Date
Washington State Departmen	t of Health	
Signature	Title	Date
Kitsap County Health Di	strict	
Signature	Title	Date
Tacoma-Pierce County Health I	Department	
Signature	Title	Date
Foundation for Health Care	Quality	

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### VERSION CONTROL LOG

DATE	VERSION	DESCRIPTION	Author
11/8/05	1.0		Linda Lekness
11/10/05	1.1		Linda Lekness
11/15/05	1.2	Background, communications strategy, scope, and evaluation	Linda Lekness
11/17/05	1.3	Edits from 11/16 meeting	Linda Lekness
11/18/05	1.4	Reorganization of strawman	Linda Lekness
11/23/05	1.5	Comments and Recommendations	Dave Ross
4/18/06	2.0	Reorganization according to consensus Table of Contents and incorporation of existing sources and new material	Laura Ripp
10/5/06	3.0	Narrowed scope to reflect pilot implementation and evaluation through Dec '07. Incorporated agreements specified by pilot implementation partners. Submitted as final draft.	Laura Ripp
1/4/07	4.0	Updated content to include current Charter participants and signatories. Added a clarifying purpose statement to the Signature Page; made minor editorial and formatting improvements.	Laura Ripp

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#### GENERAL NOTES ABOUT THE PROJECT CHARTER

#### **Charter Purpose**

The project Charter is the formal reference for shared assumptions intended to guide and define a specific period in the ODIN initiative; providing a clear statement of scope in unambiguous, high-level terms. The project Charter is intended to document shared perspectives on specific essential details of why the project is important, how the project will be conducted, how decisions will be made, any known circumstances contributing to non-participation and other limiting factors and constraints. In addition, the Charter provides a high-level baseline of the project timeline and budget and identifies major events, milestones, the project's end deliverables and stakeholder contributions to achieve them.

The Charter, in addition to the detailed project plan, will be referred to throughout the project as a reference for stakeholders to initial project parameters, as a tool to support negotiation and agreement on any changes in scope or objectives and, overall, to assure that goals for this defined period of the project are met. In essence, the signed Charter will serve as an agreement among ODIN stakeholders that indicates what is to be accomplished and who will do it. The Charter provides formal recognition of the project and signifies leadership authorization by collaborating organizations for the designated project team to move the project forward on a defined path. As an important project reference, this Charter should be periodically updated as material changes arise.

#### **Operating Principles for Charter Development**

- 1. This Charter has been developed using a voluntary process through which active participants determine the consensus terms of engagement in the ODIN Project. The Charter Development Group (CDG) includes designated participants from organizations comprising the current ODIN Steering Committee. Organizations participating in the charter development process were permitted to withdraw at any time, at which point it was understood that the organization would no longer have representation on the Project Steering Committee. Future participation would be addressed under the direction of the standing Steering Committee.
- 2. The group made decisions by consensus. Consensus is defined as "consent to support", and not to oppose, a group decision. The group will jointly design next steps and ways to test disagreements.
- 3. The group decision-making process was driven by the clear articulation of interests by CDG members. Members worked to develop a common, clear understanding of others' rationale for a given approach.
- 4. CDG members have been encouraged to test assumptions. Group members have explained the reasoning and intent behind statements, questions, and actions and

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have been encouraged to use specific examples to reach agreement on what important words mean.

- 5. The CDG included persons with decision-making authority. In cases where designees participated on behalf of named Group members, these designees have maintained responsibility for communicating all decisions and outcomes and managing any required organizational response.
- 6. CDG member time has been respected and every effort has been made to optimize the use of time and organizational resources according to the agreed upon Charter Development Approach. A special effort was made to appropriately refine the scope of the Charter to address only critical elements of Steering Committee agreement.
- 7. Between four in-person decision-making meetings, email was the primary vehicle for notification and communication among participants. Individual phone meetings and short teleconferences were used intermittently to facilitate group progress. Going forward, a combination of teleconferences and face-to-face meetings will be conducted to support progress.
- 8. CDG members agreed to a baseline statement of public health user technical needs from which more detailed requirements are being incrementally defined. Future requirements, such as those relating to cost-effectiveness and sustainability, will be specified separately, as appropriate.
- 9. During the Charter Development process and going forward, CDG members will be encouraged to share all relevant information that could potentially impact the success of the project or their continued participation in it.

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#### 1.0 EXECUTIVE SUMMARY

#### 1.1 Project Inception

The ODIN Health Data Surveillance and Analysis Toolkit project (a.k.a. Outbreak Detection Information Network) was conceived to enhance public health preparedness and response capabilities. To date, the project has been funded by the Department of Defense to help evaluate the effectiveness of combining civilian and military health indicator information in order to detect and respond to both bioterrorism events and other critical health trends such as avian flu and SARS. One of the major goals of the project is to produce a product that will have extensive functionality for the public health community and provide a long term toolset for other public health epidemiological activities.

ODIN's development occurs in a parallel timeframe with ongoing implementation of the Department of Defense's Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) system. This system and other syndromic surveillance applications have been implemented by the Washington State Department of Health (DOH) as well as other local health jurisdictions (LHJs), several which are participants in the ODIN pilot implementation. Therefore, another important goal of the project is to evaluate ODIN's added value to state and local surveillance and analysis capability and capacity.

The ODIN Project was initially proposed by Paladin Data Systems and funded by DOD in early 2003 as a research initiative. Additional funding was awarded to continue the project with current funding available through December 2007. Seattle-based Foundation for Health Care Quality, a 501(c)3 health information collaborative, has provided public-private sector facilitation among Paladin, DOH, and participating LHJs.

#### 1.2 Project Purpose and Description

At this stage, the project is focused on pilot implementation and evaluation of the ODIN Health Data Surveillance and Analysis Toolkit (Toolkit) in public health settings. The Toolkit will provide a set of tools for responsible organizations to assist in the gathering, analysis, and response to syndromic and other health surveillance information. In addition to syndromic reporting and analysis, the envisioned Toolkit implementation will offer the capability to receive, process, and forward Washington State Department of Health (DOH) reportable information, thereby allowing various information providers to take advantage of the time and cost savings afforded by having a single point of information exchange available for numerous reporting requirement types.

The ODIN Toolkit will offer a variety of analysis tools and visualization techniques allowing for complex statistical, spatial, and temporal analysis and display of the

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information within the system. The Toolkit will not only support a number of analysis tools "out of the box", but provides the framework for users to develop their own tools and extensions, and to share those extensions with others in the project community.

Above all, this Toolkit will offer state and local public health agencies a region-wide view of the information in the system, integrating and displaying data without limitations that may otherwise be imposed by political or organizational lines. Further, Washington's unique geography and concentration of DOD facilities and personnel require a view not only across county lines, but also inside and outside the gates of military facilities. This region-wide view will improve the quality of health care management for all participating organizations.

#### 1.3 Participants

The participating organizations represented on the Steering Committee for this pilot implementation and evaluation project and their respective roles include:

PARTICIPATING ORGANIZATION	Key Project Role/s
Washington State Department of Health	Pilot Hosting Entity; Infrastructure/Technical Management
Kitsap County Health District	LHJ Data Sharing Partner (pilot)
Tacoma   Pierce County Health Department	LHJ Data Sharing Partner (pilot)
Seattle-King County Department of Public Health	LHJ Interested Observer and Ad Hoc Advisor
Paladin Data Systems	DOD Contractor; Toolkit Developer; Technical Project Manager
Foundation for Health Care Quality	Subcontractor; Community Facilitator

#### 1.4 Objectives

The agreed upon approach for this unique project is to pursue technical development of the ODIN Toolkit in parallel with a limited pilot implementation and subsequent evaluation by public health participants. Specific objectives to be accomplished in the relevant period of this Charter include:

1. Take immediate steps to implement the current version (v2) of the ODIN application and evaluate its effectiveness as a tool to enable local health

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jurisdictions to achieve a regional view of data about public health activity and events.

2. Beginning no later than December 1, 2006, define a category of influenzalike illness (ILI) to be monitored using ODIN from which to evaluate the benefit of the Toolkit in public health practice.

#### 1.5 Scope of the Charter

The scope of this Charter pertains to activities required for participating parties to conduct the ODIN Toolkit pilot implementation and evaluation occurring during the DOD-funded period from September 1, 2006 through December 31, 2007.

#### 1.6 Costs/Benefits

The <u>Project Budget</u> section offers a view of budgeted costs for the period of this Charter. Medium and long-term costs, benefits and projected value of a fully implemented ODIN Toolkit will be determined as an outcome of the pilot experience and subsequent evaluation.

#### 1.7 Participant Expectations

Project participants expect to gain sufficient understanding of the current and potential value of the ODIN Toolkit relative to other analytical solutions used for similar purposes. Further, participants expect to gain important insights into the utility of DOH-hosted surveillance infrastructure to other LHJs, both analytically sophisticated users and otherwise, as part of an ongoing effort to advance statewide public health informatics capability.

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#### 2.0 PROJECT SCOPE

#### 1.1 Background

There are several converging trends that are reshaping public health practice and effecting new requirements for health information. The 1990's ushered in a new period for communicable disease surveillance and bioterrorism preparedness that highlighted the need for a more advanced electronic surveillance infrastructure that takes advantage of current information technology and supports integration and streamlining of surveillance practices. In 1999, the Centers for Disease Control and Prevention (CDC) proposed the development of the National Electronic Disease Surveillance System (NEDSS) in partnership with public health partners and state and local health departments. Since the anthrax attacks in 2001, the United States government has put health information technology and systems on a fast track to detect, respond to and contain the impact of potential bioterrorism attacks, epidemic/ pandemic diseases and other large scale public health events. Bioterrorism funding increased dramatically as did efforts to improve public health's capability and capacity to detect and respond to the threat of bioterrorism, avian flu and tomorrow's pandemics. In 2002, the first national Syndromic Surveillance Conference was held in New York City to advance the science and systems for disease surveillance across institutional and professional boundaries. In 2004, the Public Health Information Network (PHIN) received its first funding to support CDC's vision to transform public health by coordinating its functions and organizations to enable real-time data flow, computer assisted analysis, decision support, professional collaboration, and rapid dissemination of information to public health, the clinical care community and the public. In this same span of time, the federal government began funding state and regional health information infrastructure projects as part of a broad vision for a nationwide health information network to improve quality, safety and accountability for health care. These initiatives require significant advancements in technology and information infrastructure to effectively collect, analyze and interpret massive amounts of data about health incidents and trends among individuals and populations.

The ODIN Health Data Surveillance and Analysis Toolkit project (a.k.a. Outbreak Detection Information Network) was conceived to help evaluate the effectiveness of combining civilian health indicator information with military health indicator information in order to detect and respond to both bioterrorism events and other critical health trends such as avian flu and SARS. ODIN development has been funded by the Department of Defense, initially as a research project. ODIN offers tools to support analysis of very large databases including the emerging science of syndromic surveillance, which uses the information gathered in initial health encounters such as emergency room visits in order to predict disease outbreaks days to weeks ahead of clinical certainty from laboratory results. Syndromic surveillance is not yet an accepted scientific method, and one of the purposes of the ODIN project is provide additional information and experience to evaluate it relative to a wide spectrum of methodologies. ODIN is also unique in the fact that it

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is not geo-politically bound, but is designed with the capability to provide visibility across geographic boundaries. Thus, one of the major goals of the project is to produce a product that will have extensive functionality for the public health community and provide a long term toolset for other public health epidemiological activities.

ODIN's development occurs in parallel to ongoing implementation of DOD's Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) system. This system and other syndromic surveillance applications have been implemented by the ODIN stakeholder group including Washington State Department of Health as well as several local health jurisdictions in the state. Therefore, another important goal of the project is to demonstrate ODIN's added value to state and local surveillance and analysis objectives.

Technically, the first key component of ODIN is a dynamic data import engine. In order for ODIN to operate, it requires data from a wide variety of sources. It is important in the design of ODIN that information providers be able to supply information in the format and method that is easiest for them, with the ODIN toolkit providing the flexibility to adapt to various input streams. ODIN is therefore designed to accept data in virtually any format by using advanced information processing, analysis and quality control techniques. The second technical component of the ODIN toolkit is a secure data store. The secure data store is at the heart of ODIN's ability to use statistically analyzed information from the past to detect and warn of anomalous trends in health indicator data. While one of the primary functions of ODIN is to generate alerts from current trends in health indicator data, its ability to analyze different periods in time make it an extremely valuable tool in analyzing disease outbreak information from the past. ODIN will provide a number of user interfaces, flexible display features, temporal mapping capabilities, alerting and notification capabilities, data security and other subcomponents to support overall functionality. ODIN's flexibility is an important attribute to its inherent value to public health so its purposes may be expanded as needs are identified.

Three phases of development funding have been received. As part of the initial funding for ODIN, application design was undertaken with varying levels of public health input. Also, the University of Washington received a grant leading to development of the Center of Excellence for Public Health Informatics which may have a future role in related research. The second phase of funding has supported ODIN technical application development and is nearing completion. Today, a group of public health partners and other stakeholders have committed to be firmly engaged in the third phase of the project based on the agreements advanced in this Charter. Today, ODIN has a development funding source, a project team, a technical development team, and a named group of stakeholders who have agreed to implement and evaluate ODIN in a pilot environment hosted by the Washington State Department of Health.

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#### 1.2 Summary of Project Boundaries

This pilot implementation and evaluation project is bounded by three major elements: (1) participating organizations; (2) types of information exchange; and (3) policy and legal parameters.

#### Participating Organizations

Six organizations comprise the project Steering Committee and serve in various capacities as project participants. The organizational boundaries of this project include these entities and, to the extent needed, affiliated data sharing partners and other stakeholders as determined by the Steering Committee:

- A. Participants from the State of Washington public health system:
  - Washington State Department of Health (hosting pilot infrastructure)
  - Local Health Jurisdictions (LHJs)
    - Kitsap County Health District (pilot participant / data sharing partner)
    - Tacoma | Pierce County Health Department (pilot participant / data sharing partner)
    - Seattle-King County Department of Public Health (LHJ advisor)
- B. Paladin Data Systems (systems development and technical services vendor, contractor to DOD)
- C. Foundation for Health Care Quality (project sponsor, facilitator)

#### Types of Information Exchange

The collection and analyses of varied sets of health indicator data and subsequent exchange and use of information by authorized entities is a critical element at the core of this project. In an effort to define shared assumptions about user needs to accomplish these activities, the Steering Committee has agreed on a Statement of User Needs and a User Needs Fulfillment Plan intended to identify and prioritize Toolkit functions and features that may be completed within the project period with the funding available. These documents delineate the specific scope of participant expectations pertaining to types of data to be analyzed and technical development to perform a range of data analyses and information exchange functions. Some of these needs will be further defined as the project progresses to assure a clear, shared understanding about what can and cannot be done with the given timeline, budget and the DOD-contracted statement of work with Paladin. These documents are included in this Charter as Appendix A (Statement of ODIN User Needs) and Appendix B (ODIN User Needs Fulfillment Plan).

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#### Policy and Legal Parameters

This project exists in an expanding continuum of health data exchange activities under consideration at federal, state and local levels in both the public and private sectors. As such, the policy and legal basis for health data exchange is evolving. The information collection, analysis and exchange conducted in this project will be subject to current and relevant laws, data sharing agreements and organizational policies. Stakeholders will work together through the ODIN Steering Committee and with their community data sharing partners to identify circumstances in which additional policy and/or legal provisions may be desired or required. The Steering Committee will identify and discuss policy and legal issues as they surface during the ODIN pilot implementation and evaluation. This group will confer with legal counsel and policy-making bodies as required.

#### 1.3 Project Goals and Key Objectives

The ODIN Steering Committee has come together to implement a statewide disease surveillance and analysis toolkit with an initial focus on Washington's Puget Sound region. The goals of this information system project include:

- Advance public health capability and capacity to effectively detect and respond to a meaningful range of public health events using both routine and novel data sources;
- Assure that the individual and collective needs of key stakeholder organizations are met as they pertain to assuring the value of the ODIN toolkit in public health practice;
- c. Improve organizational and management functions required to support public health-private sector partnering on large information technology projects and health data sharing activities.

Specific objectives for the next 12 months, i.e., the period of this Charter, reflect technical development of the ODIN Toolkit in parallel with a limited pilot implementation. Evaluation planning activities will also be undertaken during this time. Specific objectives to be accomplished in the period of this Charter include:

- **OBJECTIVE 1.** Take immediate steps to implement the current version (v2) of the ODIN application and evaluate its effectiveness as a tool to enable local health jurisdictions to achieve a regional view of data about public health activity and events.
- **OBJECTIVE 2.** Beginning no later than December 1, 2006, define a category of influenza-like illness (ILI) to be monitored using ODIN from which to evaluate the benefit of the Toolkit in public health practice.

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#### 1.4 Project Timeframe and Key Deliverables

### 1.4.1 Project Start and End Points

**Current Phase** 

The relevant timeline for this project as defined in the Charter follows the availability of the third and final phase of funding to support ODIN development, testing and initial deployment. Using a set of development priorities as agreed upon by participants, this stage of the ODIN project will proceed along a timeline that begins September 1, 2006 and ends December 31, 2007.

The funded phases of the overall ODIN project as defined in the Charter and key deliverables for each phase are as follows:

- Phase I: March 1 2004 February 28, 2005 KEY DELIVERABLES:
  - a) Initial requirements definition
  - b) Initial application design
  - b) Prototype module development, version 1.0
- Phase II: March 1, 2005 June 30, 2006 KEY DELIVERABLES:
  - a) Refined requirements, version 2.0
  - b) Iterative design / application architecture
  - c) Functional pilot development, version 2.0
  - d) Test plan

Phase III: July 1, 2006 – December 2007 KEY DELIVERABLES:

- a) Refined requirements, version 3.0
- b) Pilot implementation hosted by DOH
- c) Iterative development and unit testing, version 3.0
- d) Final testing and debugging
- e) Training plan
- f) Evaluation plan
- g) Production product
- h) User manual/system documentation

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# 1.4.2 Key Timing Considerations, Constraints and Interdependencies Key timing considerations may be summarized as follows:

- "Phase III" funding for this project as it is currently defined ends December 31, 2007. All development, testing, support and training by Paladin Data Systems must be completed prior to this time. At the close of Phase III funding, public health stakeholders must be able to determine what role the ODIN Toolkit could have in building public health analytic capability and how the Toolkit may be sustained. The transfer of any legal rights to the Toolkit and/or derivative works would be defined through a separate process.
- Washington State Department of Health, Kitsap Health District and Tacoma | Pierce County Health Department have agreed to participate in a DOH-hosted pilot implementation during the Charter period. Data sharing during this time is dependent on technical feasibility, appropriate data sharing agreements, and resource availability. Further, evaluation of the Toolkit during this period is dependent on sufficient health indicator data being made available through participating LHJs and their data sharing partners.
- Seattle-King County Department of Public Health is unable to participate in the pilot implementation described in this Charter primarily due to the need to address other organizational priorities. Agency leadership has agreed to remain on the Steering Committee, to continue to stay current on ODIN progress, and to contribute perspective on evaluation issues as requested.

#### 1.5 Assumptions and Constraints

#### 1.5.1 Assumptions

- This Charter assumes a 12-month timeline which includes developing, testing, and piloting ODIN at DOH and certifying the ODIN Toolkit for production use. At the end of this project as defined in the Charter, the production Toolkit may be transitioned to the Department of Health.
- Each participant has different existing capabilities and may have different sets of needs that they would like to meet with this project. It is assumed that the degree to which ODIN does or does not meet stakeholder needs provides direct insight into the immediate and longterm value proposition for the Toolkit.
- The benefit of syndromic surveillance as a detection method has not been scientifically proven, but it is hoped that the proposed system will be shown to be of benefit in the event of an outbreak or epidemic and, further, to support routine surveillance activities as feasible.

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- The Toolkit functionality will be leveraged to perform other data analysis activities as part of assessing its overall value to public and private sector users and stakeholders.
- Due to unique circumstances involving stakeholder use of ESSENCE and other surveillance and analysis tools, some duplication of existing functionality is unavoidable. Further, there may be benefits that this project can realize that are beyond those of syndromic surveillance systems alone, for example, two-way communications between public health and hospitals, improvements in analysis of reportable conditions, among others. As such, understanding the advantages and disadvantages of each infrastructure component, separately and together, will be an important aspect of evaluation.

#### 1.5.2 Constraints

- Paladin Data System is under contract to DOD for a specific statement of work at a defined funding level. While DOD's objectives include advancing public health capabilities, there may be other contract deliverables and/or circumstances that Paladin will be compelled to address that may or may not be aligned with public health priorities.
- Continued participation in this project requires public health stakeholders to carefully balance a number of competing factors. As such, conditions that should be met to ensure public health participation include: (1) Adequate resources will be made available; (2) information exchange must be technically feasible and acceptable to LHJs and clinical data sharing partners; (3) the value and benefits of the Toolkit must justify participation; and (4) project decision-making must support the advancement of public health interests. The perceived imbalance of any of these conditions may be cause for stakeholder withdrawal.

#### 1.5.3 Implications

- Perhaps the single most important implication inherent in the stated assumptions and constraints is the need to adhere to realistic expectations about project scope and the level of participant involvement. Proactive project and relationship management will be critical to project success during the period of this Charter, and beyond as applicable.
- The Steering Committee understands that other public health work and competing initiatives will not necessarily remain stable during the project period and such activities may impact public health partner participation. As a routine practice, timely, effective communication should be used to facilitate progress with an emphasis on adherence to an agreed upon schedule to the greatest extent possible. However, project managers would be wise to anticipate intermittent delays and build some slack into project timelines.

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- Public health stakeholders have a range of surveillance systems and capabilities and several have current implementations of syndromic surveillance systems and/or use DOD's ESSENCE system supported by the Johns Hopkins University Applied Physics Laboratory. Understanding complimentary and potentially duplicative functionality will be an important area of focus in the evaluation of the Toolkit's relative value to public health. Public health stakeholders should assess the Toolkit's total contribution to public health information infrastructure relative to the near- and medium-term cost to support its added value when compared to comparable infrastructure options at state and local levels. The demonstration and quantification of Toolkit value will be essential to build a case for future support and broad adoption by LHJs and their data sharing partners across the state.
- For many reasons, the inception, design and development phases of the ODIN initiative reflect an unconventional approach to collaborative information systems development. Going forward, stakeholders have an opportunity to use the testing and deployment phases of this project to advance their collective competence in the practical application of sound informatics principles in a collaborative environment. Special attention should be given to technical issues, such as data integration and the adoption of standards; policy and legal issues, such as data sharing agreements; and shared IT governance and decision-making to advance cross-programmatic public health information infrastructure.

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#### 3.0 Project Governance and Accountability

#### 3.1 Governance and Leadership

Governance and leadership issues are of critical importance to this IT project, especially due to the atypical nature of its inception, funding and early management. During the current project timeline as defined in the Charter, participants in the Steering Committee will have both shared and distinct roles in directing the project depending on their chosen level of involvement in implementation and evaluation activities. All Steering Committee members will contribute to the determination of whether or not the ODIN Toolkit adds sufficient value relative to a larger public health IT portfolio to deploy, operate and maintain in a production environment at the close of this project. Collectively, the Steering Committee is responsible for both short-term, technical and operational decisions coupled with longer-term decisions regarding feasibility, desirability and sustainability.

Governance and leadership responsibilities are focused on guiding the stewardship of ODIN in the context of its relevance as a vital public asset. That is, as a project paid for with government funds intended to be clearly supportive of protecting the health of populations, the governance and leadership roles of the ODIN Steering Committee members named in this Charter include both short-term responsibilities and longer-term considerations. Table 1 describes specific governance and leadership roles of the ODIN Steering Committee.

Table 1. ODIN Steering Committee Governance and Leadership Roles

GOVERNANCE AND LEADERSHIP ROLES	ACCOUNTABLE STAKEHOLDERS
Determine project feasibility and approve feasibility decisions	<ul> <li>Department of Defense (budget)</li> <li>Public Health (business value, implementation, adoption)</li> <li>Paladin (technical)</li> </ul>
Define and manage the project to control inherent risks	<ul><li>Foundation for Health Care Quality</li><li>Paladin</li></ul>
Develop and execute software development and testing plans	■ Paladin
Review prototypes to validate Toolkit concepts, architecture and functionality and help inform how testing will be accomplished	■ Public Health

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GOVERNANCE AND LEADERSHIP ROLES	ACCOUNTABLE STAKEHOLDERS
Identify relevant policy and legal issues and take appropriate action to resolve them	■ Public Health
Determine how the project recovers costs or adds measurable value or positive costbenefit to the business (public health) functions it is designed to perform	■ Public Health
Inform the approach to acquiring data from data sharing partners	■ Public Health
Identify the need and role for private contractors under performance contracts	■ Public Health
Define when independent experts should assess, evaluate and report on various aspects of the project to stakeholders. Such experts may assess, evaluate and measure:	■ Public Health
Technology solution	
<ul> <li>Infrastructure options</li> </ul>	
<ul><li>Analytics</li></ul>	
Data quality	
<ul> <li>User satisfaction</li> </ul>	
Cost performance	
Other parameters as identified	
Contribute to anticipated cost projections for maintenance and update of the toolkit	■ Paladin
Create a sound business plan for the project to describe how it will be sustained	<ul><li>Public Health</li><li>Foundation for Health Care Quality</li></ul>
Make recommendations for project funding continuation	<ul><li>Public Health</li><li>Foundation for Health Care Quality</li></ul>

# 3.2 Decision Making Structure and Process

# Decision-Making Structure

Building on governance and leadership roles as defined above, an agreed upon decision making structure and processes will help assure that each project

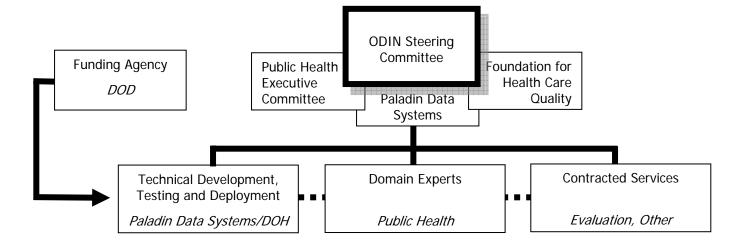
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stakeholder has an opportunity to contemplate the consequences of new, proposed approaches or changes in an existing project parameter. The Steering Committee's approach to decision-making encourages each stakeholder to assess the impact of a new proposal or change on his/her organization, on project outcomes and other stakeholders, and to constructively challenge a final decision.

The decision-making practices adopted during the ODIN project timeframe, as defined in the Charter, take into account the need for continuity of leadership and governance to achieve project objectives while also setting a solid precedent for future activities. Figure 1 describes the proposed structure, which recognizes current participants while also offering a framework to support ongoing deliberations, decision-making and evolution of the initiative.

Figure 1. ODIN Project Decision-Making Structure



#### Decision Making Processes

ODIN stakeholders have agreed to the following statement of objectives to help drive the spirit and approach to effective Steering Committee decision-making and conflict management:

#### ODIN Steering Committee Decision-Making Objectives

The ODIN Steering Committee agrees:

- To adopt guidelines that support achievement of consensus on all decisions put forth for a vote by the ODIN Steering Committee where consensus is defined as "consent to support", and not to oppose, a group decision.
- To implement a decision-making process that accommodates and considers differences in Steering Committee member opinions. Through this process,

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Steering Committee members will focus on articulating their interests rather than be bound by their positions; members will balance advocacy for specific results with inquiry to clearly understand the rationale for alternative approaches.

To establish a decision-making precedent for future governance activities of the ODIN Steering Committee.

In support of achieving decision-making objectives, the following guidelines have been agreed upon by the ODIN Steering Committee and will be used to foster a logical, orderly approach to decision-making and conflict management.

#### ODIN Steering Committee Decision-Making Guidelines

- 1. Reasonable effort will be made to achieve a consensus decision among the group without use of a voting process. Consensus will be achieved when all organizations indicate they feel that discussion has been fully carried out and they are willing to support a proposed decision.
- 2. A vote may be called for when this appears necessary to move the process along without undue loss of time.
- No decision will be voted on prematurely, that is, the group will revisit and adjudicate decisions as long as productive debate and discussions continue.
- 4. At the discretion of the group, agreed upon criteria and decision-making methods will be applied to support specific decisions.
- 5. Each participating organization will have one vote to be cast by an authorized representative or their designee.
- 6. The core voting group will be identified. Membership by any person representing an organization is voluntary; an organization and/or individual may choose to formally disengage from the group for any reason and at such time will not be included in subsequent decision-making processes.
- 7. A voting quorum, either physically present or participating by phone or by proxy, is a simple majority of the voting organizations.
- 8. The group may decide to postpone an important vote if participation is felt to be too low.
- 9. A 2/3 majority vote of the organizations present or participating by phone or by proxy is required to approve group decisions.
- 10. Votes will be conducted by voice vote of group members in attendance. A roll-call vote can be requested by any voting member if the voice vote is considered close.
- 11. Votes on important matters will be announced in advance of a meeting.

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- 12. Proxy voting is permitted. Proxy votes may be delivered in person by a designee or in writing (email is acceptable) prior to the vote. Proxy votes are allowed only for specific motions that are announced in advance of a meeting.
- 13. The group will vote on decisions that are grounded in well-formulated issues and supported by an appropriate interval of time to review materials, identify, discuss and clarify relevant matters.
- 14. The group may require budget analyses to determine the potential impact of decisions and/or other financial considerations. In such cases, a budget impact (or other) analysis must be provided to inform decision making.
- 15. As needed, Robert's Rules of Order will be applied to conduct a meeting.

#### 3.3 Responsibilities for Issues Identification and Management

A shared issues identification and management process will be adopted for communicating relevant project issues to the Steering Committee, prioritizing them and effectively working toward successful resolution. In general, Steering Committee members or their designees will represent their respective organizations in issues identification, management and decision-making as follows:

#### Public Health

The Washington State Department of Health will be responsible for identifying and communicating issues related to its technical infrastructure and all related pilot implementation issues that impose requirements on participating LHJs. In the DOH-hosted pilot implementation, LHJ participants, Kitsap County Health District and Tacoma | Pierce County Department of Health, will work with DOH to draw on their respective technical support personnel and epidemiologists to address issues and help inform Steering Committee decisions pertaining to data feeds, algorithms/code sets/analyses, Toolkit functionality and user training. All public health participants will also drive decisions pertaining to participation of data sharing partners, Toolkit evaluation planning and execution, determination of the Toolkit's overall value to public health, and all decisions pertaining to sustainability.

#### Paladin Data Systems

Paladin's role in the decision-making process will be focused on collaboratively addressing technical issues pertaining to Toolkit development, testing, training and transitioning ODIN software into different processing environments as directed by the Steering Committee. Paladin will provide technical support for the Toolkit during the pilot implementation period at DOH and Paladin will be responsible for surfacing and communicating any questions it may have to clarify Toolkit

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requirements, development and testing issues. Paladin will depend on public health participants to maintain timely bilateral communication regarding support and development needs. Paladin will allow adequate, yet defined time periods for public health stakeholder responses. Paladin's role in decision-making will end at the close of this project period, as defined in the Charter, or another time as determined by the Steering Committee.

#### Foundation for Health Care Quality

In its project management role, the Foundation for Health Care Quality will be responsible for decisions regarding coordination and communication among project stakeholders. The Steering Committee will advise the Foundation on communication with external entities as appropriate. In this role, the Foundation will also help inform the Steering Committee of issues that impact project timing, budget and/or achievement of stated objectives.

In its consultative role, the Foundation will provide support for biostatistical tasks such as development of proposed definitions of influenza-like illness (ILI) categories and the related use of various data types in the Toolkit. The Foundation will also provide support for user training activities during the pilot implementation and evaluation period.

In its facilitative role, the Foundation will be responsible for effectively communicating and facilitating the satisfactory resolution of issues as directed by the Steering Committee. Should there be an issue that cannot be satisfactorily resolved after reasonable attempts; the Foundation will be responsible for considering use of an objective third party to help negotiate a workable solution. Should any stakeholder decide to withdraw its participation from the project for any reason, they should report this decision to the Foundation.

Looking into 2008, public health stakeholders will have assessed the results of the ODIN Toolkit evaluation to help define its value and overall guidelines for any additional development, testing, and refinement needed. The Steering Committee will then be in a position to make decisions about encouraging expanded participation in a production environment and future infrastructure requirements to accommodate the core technology and how it is operated, maintained and funded.

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# 4.0 PROJECT RESOURCES

# 4.1 Project Roles

The project includes a range of roles that span public and private sector participants. Current primary project roles are described in Table 2 below.

**Table 2. Primary Project Roles** 

TITLE	PRIMARY ROLE AND ACTIVITIES	STAKEHOLDER
Funding Agency	Provide funding to support project activities as defined in approved statements of work.	<ul><li>U.S. Department of Defense</li></ul>
Project Sponsor	Coordinate and facilitate collaborative project activities and provide consultative support as needed. Assist in issues identification, management and resolution.	■ Foundation for Health Care Quality (FHCQ)
Project Steering Committee	Identify and manage project issues and serve as the project's primary collaborative decision-making body representing key stakeholders and participants.	<ul> <li>Washington Department of Health (DOH)</li> <li>Tacoma   Pierce County Health Department</li> <li>Kitsap County Health District</li> <li>Paladin Data Systems</li> <li>Foundation for Health Care Quality (facilitator)</li> <li>Seattle-King County Dept. of Public Health (advisory)</li> </ul>
Public Health Domain Experts and End Users	Inform the technical design and development; provide functional requirements to reflect sound analytic and epidemiological methods and support public health practice; contribute to priority setting; provide guidance on relationships with health data sharing partners and health data acquisition strategies; and determine Toolkit value and the feasibility of long-term use.	Washington Public Health as represented by:  Washington State Department of Health  Tacoma   Pierce County Health Department  Kitsap County Health District
Biostatistician	Provides consultative support for Toolkit analytical functionality.	<ul><li>Foundation for Health Care Quality (staff)</li><li>Other resources as identified</li></ul>

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TITLE	PRIMARY ROLE AND ACTIVITIES	STAKEHOLDER
Senior Network Administrator	Review and set up infrastructure; establish and test data feeds	■ DOH ■ Paladin
Technical Project Manager	Manage staff, reports, scope, deliverables, schedule, and budget related to the DOD contract and technical build	Paladin
Senior Advisor	Provide technical direction and advice on feasibility to meet business needs	Paladin
Senior Developer/Designer	Design and develop application including analysis	■ Paladin
Developer	Develop application modules and interfaces including data stream extractions	Paladin
Database Administrator	Database set up, tuning, performance, and maintenance to support the application	Paladin
Graphics Specialist	Develop graphical interface and any brand items such as logos, etc. for the project	Paladin
Tester	Test system and assist with specification documentation	■ Paladin
Trainer	Develop training plan and deliver training sessions	<ul><li>DOH</li><li>FHCQ</li><li>Paladin</li></ul>

#### 4.2 Public Health Executive Committee

The ODIN Executive Committee includes the following Steering Committee members that represent their respective public health organization and have the authority to make decisions on its behalf.

- Jude Van Buren: Assistant Secretary, Washington State Department of Health
- Dr. Vic Harris, Deputy Director, Tacoma | Pierce County
- Dr. Scott Lindquist, Director of Health, Kitsap Health District

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Executive Committee roles and responsibilities include:

- A. Contribute to the success of the project, in which they have a vested interest;
- B. Serve as key decision makers on critical issues including those pertaining to decisions with strategic, operational and budget implications;
- C. Support Work Group requests for assistance on critical issues; and
- D. Provide guidance and supervision of Work Group members from their respective organizations as needed to support achievement of project objectives.

#### 4.3 Paladin Data Systems

Serving as the technology contractor for this project, Paladin will be represented on the Steering Committee by Gary Macy, Chief Technology Officer.

#### 4.4 Foundation for Health Care Quality

During the timeline described in this Charter, the collaborative aspects of the ODIN project are being supported by the Foundation for Health Care Quality. Foundation roles and responsibilities include providing a collaborative framework and environment in which to convene, facilitate and otherwise support the overall achievement of project objectives. Foundation staff and assigned contractors will manage the collaborative aspects of the project, including but not limited to, convening meetings, producing meeting minutes, providing biostatistical domain expertise and exploring specific technical and non-technical issues as required or requested by project participants. In this role, the Foundation will be represented on the Steering Committee. The following project leaders, managers and staff will support the project as it is currently defined:

- Andy Fallat, Project Executive Sponsor and CEO, Foundation for Health Care Quality
- Peter Dunbar, MD, ODIN Project Principal Investigator
- Linda Lekness, ODIN Project Manager, Foundation for Health Care Quality
- Ian Painter, PhD, Biostatistician, Project Staff, Foundation for Health Care Quality

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#### 4.5 Working Groups

Working groups include participant personnel grouped according to their specific expertise to accomplish defined aspects of the project. Today, these working groups are loosely organized around technical issues and public health practice issues. Participation will be adjusted as needed to accomplish project goals. Current working group participants are listed.

Technical Development, Testing and Deployment Work Group:

- Phill Lowe, Epidemiology Data Systems Manager, Informatics Program, Washington State Department of Health
- Michael Davisson, IT Director, Public Health Labs / WEDSS Project Director, Washington State Department of Health
- Scott Horn, Information Services, Kitsap Health District
- Anne Harvey, Technical Project Manager, Paladin Data Systems
- Ian Painter, PhD, Biostatistician, Foundation for Health Care Quality
- LHJ technical support as assigned
- Paladin developers and analysts as assigned

#### Public Health Domain Work Group:

- Jo Hofmann, MD, State Communicable Disease Epidemiologist and CD Office Director, Washington State Department of Health
- Judith May, Bioterrorism Surveillance and Epidemiology Manager, Communicable Disease Epidemiology, Washington State Department of Health
- Donna Duffy, Epidemiology Surveillance Coordinator for DOH Bioterrorism, Washington State Department of Health
- Eva Crim, Health Information Resource Program Manager, Kitsap Health District
- Nicola Marsden-Haug, Epidemiologist II, Washington State Project Coordinator
- Nigel Turner, Public Health Manager, Communicable Disease Control, Tacoma – Pierce County

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#### 4.6 Contractor Resources

Contractor resources will be engaged from time to time as required to support specific project needs. While some work group staff are contract personnel to stakeholder organizations, this resource category is primarily reserved for contractors engaged to support specific aspects of the project. The Foundation for Health Care Quality contracts with the following personnel in a consultative capacity and to assist in this project:

Laura Ripp, Charter editor

Other contractors will be defined by the Steering Committee.

#### 4.7 Other IT Personnel and Resources

This category of resources will be used to describe additional personnel that may contribute to the project in less structured roles. Currently, one person is providing facilitation assistance to the project during the Charter development process and may potentially serve in an ongoing role:

 Bud Nicola, MD, MHSA, FACPM, Director, Community-Oriented Public Health Practice Program Faculty, Northwest Center for Public Health Practice Senior Consultant and CDC Assignee University of Washington School of Public Health and Community Medicine Department of Health Services

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#### 5.0 EVALUATION

The ODIN Steering Committee agrees that evaluation of the Toolkit is essential to gain insight into its actual value to public health and the likelihood of statewide adoption and use. The information and experience gained through initial evaluation activities will be used in part to develop a long term plan for ongoing evaluation of the Toolkit, including an approach to update coders and algorithms. Details of a formal evaluation plan are to be developed during this Charter period with DOH taking the lead on plan design for review, comment and approval by the Steering Committee. The Steering Committee's guiding assumptions for ODIN evaluation include the following:

- a. Evaluation activities are intended to represent the needs of public health agencies that will rely on the ODIN Toolkit for analytical support pertaining to numerous data sets, to be defined.
- b. A detailed Evaluation Plan will be developed to support this Charter and the overall ODIN initiative and, at a minimum, will pertain to those activities that are feasible and desirable to implement during the period ending December 31, 2007.
- c. Evaluation deliverables, including but not limited to findings and implications for system development and refinement, will be shared with the ODIN Project Steering Committee and system developers.
- d. Recommended changes to ODIN will be assessed as to their priority as defined by public health users and managed according to a formal change control process as defined by system developers.
- e. Evaluation will be conducted in parallel with pilot testing and implementation of ODIN, to be hosted by the Washington State Department of Health for use by the State and participating local health jurisdictions (LHJs).
- f. The context for evaluation is the integration of real-time data feeds across independent organizations and agencies that may have different surveillance and analytical systems in use. Further, ODIN's contribution to achieving the goal of regional surveillance should be reflected in the evaluation plan.
- **g.** The funding and mechanism/s for conducting evaluation activities will be determined by the ODIN Project Steering Committee. Funding must be derived from existing project funds or some other readily available, known funding source that can be encumbered to support a defined evaluation scope of work.
- **h.** The final version of this Evaluation Approach document will be incorporated into the *ODIN Health Data Surveillance and Analysis Toolkit Project Charter* as an addendum representing the consensus agreement among the ODIN Project Steering Committee.

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The ODIN Toolkit Evaluation Plan will incorporate questions of interest to public health participants which include, but are not limited to the following:

- 1. Can each participating county (Kitsap and Tacoma | Pierce) successfully send relevant data types to DOH?
- 2. Was two-way data flow accomplished between pilot locations and DOH?
- **3.** Was someone available at each user location to look at the data?
- **4.** Is staff adequately trained to understand the data?
- **5.** Does the ODIN Toolkit give public health users a view of the data that is new and useful?
- 6. Did each participating county draft a response plan?
- **7.** Can public health use the Toolkit to create insight into certain issues and events that actually change/improve public health response?
- 8. How technically robust is the Toolkit?
- **9.** Does the ODIN Toolkit give public health added value? If so, is the value added adequate to justify ongoing support?

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# 6.0 RISK MANAGEMENT

# 6.1 Project Risk Identification, Management and Mitigation Plan

Table 3 describes current project risks, their potential for occurrence and key steps to mitigate and manage such risks.

Table 3. High-Level Project Risk Assessment

	Major Project Risks	POTENTIAL OCCURRENCE (H, M, L)	MANAGEMENT / MITIGATION PLAN
1.	Project Steering Committee does not agree (as a whole) to the project scope.	M	Commit to define user requirements throughout the design and development phases of the project and ensure project delivers a solution that meets individual and collective requirements.
2.	State and county health agencies have disparate needs that may compromise the overall project objectives.	M	Define and document each participant's individual needs and work toward a consensus statement of needs for a regional solution.
3.	Knowledgeable staff leaves early in the process (especially public health and technical staff.)	M	Intermittently reaffirm participation as required to actively identify and manage risk and to constructively address required changes.
4.	Hospital relationships with local public health agencies could be compromised by proposed changes.	M	Work with LHJs to ensure communication channels and messages are established prior to any changes occurring.
5.	Current hospital data stream extractions cannot effectively accommodate new functionality.	M	Clearly define system and business requirements to allow for adequate planning, review, and additional effort required to involve hospitals.
6.	Steering Committee members may be too busy to provide timely decisions on project efforts.	н	Provide adequate feedback time for response and comments and identify the Steering Committee as the ultimate decision-making body.
7.	Resource constraints may prevent or seriously limit public health stakeholder involvement in Toolkit implementation and evaluation.	M	Provide funding according to an equitable, agreed upon project budget allocation to support public health participation in Toolkit implementation and evaluation activities.

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Risk management activities are intrinsically anticipatory, therefore, as appropriate; the Steering Committee will consider future deployment decisions to manage risks related to this initiative in an effort to promote the best possible outcomes. In anticipation of a scenario in which the ODIN Toolkit has been determined to provide sufficient added value to public health to warrant continued investment and production deployment, the following risk management practices will be employed:

- Review and anticipate implementation challenges following the pilot period. This includes reconciling the Toolkit with practical use (business process) requirements to help assure the product meets intended user objectives and to promote adoption.
- Clearly identify security, bandwidth and internal systems interface considerations in the pilot stage.
- Evaluate hardware performance in the existing production environment rather than rely on manufacturer (or other) specifications.
- Ensure that installed hardware meets or exceeds specifications.
- Assure adequate staff resources.
- Assure adequate funding is available to meet future project needs.
- Include informed overestimates for time and costs to support troubleshooting and resolving unforeseen technology issues.
- Develop an IT customer service agreement before implementation.
- Ensure sufficient training preparation time as well as sufficient training time.
- Complete training activities according to a well designed plan.
- Before full implementation, clearly define the transitions from the vendor's project team to the vendor's product support help desk to the final deployment model including user support, maintenance and operations.
- Assure follow-up and provide adequate user support during the initial phases of regional/statewide rollout.

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#### 7.0 COMMUNICATION

#### 7.1 Communication Principles

The overall principles that will guide ODIN project communications include:

- Use the Project Charter to keep current and reinforce shared agreements on project goals and the strategic significance of the effort.
- Work collectively to increase understanding among all stakeholders and expose and clarify areas of misunderstanding.
- Support tactical coordination among project managers, project participants, intended users, and developers.
- Regularly recognize and acknowledge project milestones.
- Express the importance of stakeholder groups by demonstrating that their interests are being addressed.
- Support relationship-building through timely, effective, bidirectional communication with key stakeholders and other interested parties.

#### 7.2 Approach to Internal and External Project Communication

Project communication includes both internal and external dimensions. The approach to internal communication includes consideration of the stakeholders, their information needs, the format and frequency of such communications, and the process that will be most useful for conveying the needed information. The following communication activities will be used to ensure accurate and appropriate information dissemination within the team:

- Project Charter approval and use as a living reference document to reinforce stakeholder agreements.
- Face-to-face project status and information-sharing meetings as needed to support group cohesion and goal achievement.
- Conference calls and/or web conferences to review project development and issues.
- Communication content development responsibilities will be assigned by the Steering Committee. Such activities will include development and distribution of meeting minutes, fact sheets, written status reports, and project updates.

The approach to external communication is grounded in achieving consistency and clarity in formal and informal messages that may have implications for outside entities. Strategic communication planning is an important Steering Committee role especially in a scenario that implies

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possible expansion of ODIN's use by other LHJs and their health data sharing partners such as clinics, hospitals, laboratories, health systems and health data aggregators, among others. Near-term communication with external parties will be planned and conducted by the Steering Committee as required. However, the Steering Committee agrees that a more formal communication plan is needed to manage structured external messages over time. Therefore, a more formal plan will evolve according to project outcomes and as subsequent communication needs arise.

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#### 8.0 Going Forward Project Plan

#### 8.1 Project Approach and Work Plan

The ODIN pilot implementation and evaluation effort involves three major phases of work: (1) software development and testing; (2) evaluation; and (3) transition. These phases, their associated activities and the estimated timeline for performance are represented in the project work plan in Figure 2. The Steering Committee is responsible for all refinements to the work plan and will define all specific meeting dates and agendas needed to sufficiently define project details over time.

#### 8.2 Project Management and Operations Accountability

Due to the nature of the project relationships and its unique structure, there are some inherent project management challenges related to accountability for required deliverables. Paladin Data Systems retains accountability for satisfactory completion of specific contract deliverables to DOD within a defined period of performance. Paladin's responsibility includes detailed project management functions as they pertain to software development, testing, deployment and technical documentation.

Public health participants are not held to the same level of contractual accountability as Paladin. However, they have agreed to engage in the project activities described in this Charter and to make their best effort to be responsive to the timeline and requests for input where public health expertise is needed. As suggested in the work plan and throughout this Charter, Paladin will work closely with public health participants to implement the pilot environment and address refinements to finalize production-level Toolkit requirements as mutually agreed upon and as feasible within the project budget, scope and timeline. It should be noted that Public health participants have assumed responsibility for Toolkit evaluation and will take a leadership role in planning and executing this important element of the project.

The Foundation for Health Care Quality serves in an important role to bridge the discrepancy in accountability for completion of project deliverables between Paladin and public health participants. The Foundation has assumed responsibility for facilitating the clear articulation of commitments and evolving agreements among the parties for the duration of the Charter period. The Foundation is also responsible for critical collaborative project management functions including maintaining good communication among project stakeholders, convening meetings, conducting teleconferences, documenting action steps and decisions, and performing all necessary follow-up to propel the project forward according to shared assumptions.

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Figure 2. ODIN Work Plan and Estimated Timeline

# ODIN Health Data Surveillance & Analysis Toolkit ODIN Toolkit Pilot Implementation and Evaluation Timeline--September 2006 -- December 2007

2002															
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◆ = Key Milestones and Steering Committee Decision Points

➤=Activity continues beyond project timeline

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# **A**PPENDICES

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# APPENDIX A: STATEMENT OF ODIN USER NEEDS ODIN HEALTH DATA SURVEILLANCE AND ANALYSIS TOOLKIT

#### Approved by ODIN Steering Committee February 16, 2006

1. Public Health and Partners' Current User Needs (note: letters in [braces] signify cross references to the list in Appendix B: ODIN User Needs Fulfillment Plan.)

#### **USER INTERFACE**

- a. [q] Provide a single, common look-and-feel user console for the toolkit. All LHJ, DOH and data provider users will use the same tools for performing updates, data and statistical algorithm displays.
- [r, b] Provide the data providers with the same analysis capability for their data as LHJs and DOH have including access to their analyzed data via secure web sites (updated on an automated, daily basis or more frequently if necessary.)
- c. [a] Provide a Washington state regional analysis view:
  - i. DOH and LHJs will be able to see regional analyses; and
  - ii. LHJs will not have access to other LHJs data analyses unless explicitly agreed upon.

#### **ACCESS CONTROLS**

- d. [c] Include role-based security with roles for data providers, LHJs and DOH.
- e. [d] Include security protections such that one data provider cannot see another data provider's data, and one LHJ cannot see another LHJ's data.

#### ANALYSIS, VISUALIZATION AND REPORTING

- f. [i] Include current functionality used by LHJs as a part of the ODIN toolkit.
- g. [l] Include the capability to maintain an "unlimited" number of unique syndromic analysis algorithms and syndromic condition coding algorithms:
  - [h] Include the best and most current chief complaint coders and data analysis algorithms as defined by technical and academic experts in advanced surveillance methods.
  - ii. [e, g] Provide dynamic capability for multiple syndromic coders (including, but not limited to, NYC, RODS, EARS, ESSENCE) along with the ability for individual users to create, upload, modify, maintain and store customized coding algorithms.
  - iii. [j, k] Include the capability for LHJ and DOH users to easily duplicate, add, update, modify syndromic statistical analysis algorithms for event detection analysis.

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- h. [p] Include user-specific analysis capabilities; this would include simple statistics and trend analysis on data.
- i. [m] Include the capability to perform syndromic statistical analysis by both data provider location & patient residence and to map the output of these analyses.
- j. [n] Include the capability for analyses to be run at preset periods several times per day and on demand so that results can be refreshed if data are received from data providers at different times throughout the day.
- k. [v] Include automated capability to continuously evaluate data quality and promptly address problems with data. (e.g., missing or incomplete data). Users will have the ability to designate IT personnel at each data provider who will receive automated notifications when missing data need to be resubmitted.
- I. [w] Include the ability to handle different identifiers and de-identifiers, with a goal towards standardized de-identifiers and identifiers.
- m. [u] Include the ability to download the data using common data formats (e.g., .xls, .txt, .dbf, xml).
- n. [f] Include the ability to add additional data sources to the toolkit (e.g., school absenteeism, pharmacy sales, laboratory results) and develop tools for analyzing those data sources (See #2).

#### COMMUNICATION AND NOTIFICATION

- o. [s] Include automated notifications of statistical anomalies in the data, with an ability to configure the notification by LHJ (this includes who in the LHJ is notified and what constitutes a statistical anomaly). The users will select which algorithms to monitor for notification. Should be provided in the context of DOH "SECURES" communication system.
- p. [x] Provide tools for ODIN users to facilitate communication with one another to discuss aberrations detected by the toolkit. For example, users will have the ability to flag a signal that requires follow-up or might be of interest to other users, and to post a message next to that item as well as to distribute email to a selection of users who should review that signal.

#### RESEARCH AND EVALUATION

- q. [o] Evaluate existing data sources, algorithms, and coders concurrently with toolkit development to ensure that the tools available in the toolkit are relevant and are meeting user needs.
- r. [t] Include the ability to perform data extracts for research according to applicable data sharing provisions (with written approval of each LHJ, as some existing data sharing agreements with data providers may explicitly forbid use of data for non-Public Health purposes.)

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#### 2. Additional Data Sources for Potential Linkage to the Toolkit for Analysis

- a. Poison Control Data
- b. Coded Emergency Department discharge information
- c. Over the Counter Pharmacy sales information
- d. Lab data both from Data providers and commercial laboratories including the feeds from Electronic Laboratory Reporting Systems and aggregator systems such as PHRED
  - i. Laboratory reportable conditions
  - ii. Select Laboratory Test Requests
- e. Communicable Disease case reports
- f. Primary care discharge information
- g. RODS pharmacy sales information
- h. BioSense
- i. PHIMS reports
- i. School and business absenteeism data
- k. Medical examiner data
- I. EMS/911 dispatch data
- m. Other data sources as deemed acceptable by Charter Members

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# APPENDIX B: ODIN USER NEEDS FULFILLMENT PLAN

		US	ER PRIC	RITIES (*	l=higher	4=lower)
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTI	ONALITY CURRENTLY INCLUDED IN ODIN VERSI	ON 2				
1a. Provide a WA state regional analysis view (see subitems (1ai) and (1aii)	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1
1ai. DOH and LHJs will be able to see regional analyses	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	2	1	1	1	1
1aii. LHJs will not have access to other LHJs data analyses.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1
<ol> <li>Provide the data providers with access to their analyzed data via secure web sites (updated on an automated, daily basis or more frequently if necessary.)</li> </ol>	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1
<ol> <li>Include role-based security with roles for data providers, LHJs and DOH.</li> </ol>	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1
1d. Include security protections such that one hospital cannot see another hospital's data, and one LHJ cannot see another LHJ's data.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1
1m. Include the capability to perform syndromic statistical analysis by both by hospital location & patient residence.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	4	1
1q. Provide a single, common look-and-feel user console for the toolkit. All LHJs, DOH and hospital users will use the same tools for performing updates, data and statistical algorithm displays.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	4	1
1u. Include the ability to download the data using common data formats (e.g., .xls, .txt, .dbf, xml).	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1

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		US	ER PRIO	RITIES (1	l=higher	4=lower)
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTI	ONALITY CURRENTLY INCLUDED IN ODIN VERSI	ON 2				
1v. Include automated capability to continuously evaluate data and promptly address problems with data. / USER NOTES: This item is currently available in our own system as well as in the ESSENCE system, and I would argue that it is important that this feature be available immediately.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1
1e. Provide dynamic capability for multiple syndromic coders (including, but not limited to, NYC, RODS, EARS, ESSENCE) along with the ability for individual LHJs to create, modify, and store customized coding algorithms. / USER NOTES: Users must be able to create and modify the algorithms on-the-fly.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release. ODIN was designed to be expansible and modifiable. In order to actually make modifications, technical computer skills are required to link into the data structures, and code the mathematical algorithms to perform complex statistical analysis in a compatible toolset.	2	1	1	4	1-2
1g. Include the ability to create, upload and maintain the chief complaint coding algorithms by adding, editing, and deleting additional local codes and algorithms dynamically. / USER NOTES: Similar to 1e.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid-April demonstration CD-ROM's and will be available in the July 1 Version 2 Release. ODIN was designed to be expansible and modifiable. In order to actually make modifications, technical computer skills are required to link into the data structures, and code the mathematical algorithms to perform complex statistical analysis in a compatible toolset. A responsible system manager (probably the State DOH hosting agency) would control exactly what is added and modified in the core system, while individual LHJ's could perform extracts and local analysis for more esoteric studies	2	1	1	1	1
1h. Include the best and most current chief complaint coders and data analysis algorithms as defined by technical and academic experts in advanced surveillance methods. / USER NOTES: Coders and algorithms must be current to make the analytical output useful.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release. As this requirement is constantly changing as research in the field of syndromic surveillance progresses, it will have to be upgraded periodically.	2	1	1	1	1-2
1o. Evaluate existing data sources, algorithms, and coders concurrently. / USER NOTES: This is one aspect of ODIN that could serve some benefit to LHJs as we do not currently have the resources to evaluate the named elements.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	1	1	1	1	1
1f. Include the ability to add additional data sources to the toolkit (e.g., school absenteeism, pharmacy sales, laboratory results) and develop tools for analyzing those data sources.	The functionality to meet this requirement is inherent in the basic design of the ODIN system. ODIN was designed to be expansible and modifiable. While there is no system imposed limit to the number of data types and analysis tools that can be supported there are practical limits related to the "time to process" and computational intensity of the operations. It should be noted that some level of computer and information management skills will be required to accomplish these tasks. A responsible system manager (probably the State DOH hosting agency) would control exactly what is added and modified in the core system.	2	1	4	3	2

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		US	ER PRIO	RITIES (1	=higher	4=lower)
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTI	ONALITY CURRENTLY INCLUDED IN ODIN VERSI	ON 2				
Include the ability to easily modify, duplicate or update standard syndromic statistical analysis algorithms. / USER NOTES: Assume this the same or very similar to 1e.	The functionality to meet this requirement is inherent in the basic design of the ODIN system. ODIN was designed to be expansible and modifiable. That being said, the concept of "easily" is a very relative term. In order to actually make modifications, technical computer skills are required to link into the data structures, and code the mathematical algorithms to perform complex statistical analysis in a compatible toolset. A responsible system manager (probably the State DOH hosting agency) would control exactly what is added and modified in the core system, while individual LHJs could perform extracts and local analysis for more esoteric studies	1	1	1	4	1
1k. Include the capability for LHJ and DOH users to duplicate, add, update, modify syndromic statistical analysis algorithms for event detection analysis. / USER NOTES: Similar to 1j.	The functionality to meet this requirement is inherent in the basic design of the ODIN system. ODIN was designed to be expansible and modifiable. That being said, the concept of "easily" is a very relative term. In order to actually make modifications, technical computer skills are required to link into the data structures, and code the algorithms to provide the required functionality in a compatible toolset. A responsible system manager (probably the State DOH hosting agency) would control exactly what is added and modified in the core system, while individual LHJ's could perform extracts and local analysis for more esoteric studies	1	1	1	4	1
Include the capability to maintain an "Unlimited" number of unique syndromic analysis algorithms and syndromic condition coding algorithms. / USER NOTES: Could fold the word "unlimited" into 1j	The functionality to meet this requirement is inherent in the basic design of the ODIN system. ODIN was designed to be expansible and modifiable. While there is no physical limit to the number of analysis and coding systems that can be supported there are practical limits related to the "time to process" and computational intensity of the operations. A responsible system manager (probably the State DOH hosting agency) would control exactly what is added and modified in the core system, while individual LHJ's could perform extracts and local analysis for more esoteric studies	1	1	1	4	1
1n. Include the capability for analyses to be run at preset periods several times per day and on demand so that results can be refreshed if data are received from data providers at different times throughout the day. / USER NOTES: LHJs will have an immediate need to refresh the data on demand.	Data is analyzed "on-the-fly" as users request various display from the system. Currently, a separate import process accepts, aggregates, and performs some statistical processing at a fixed time, once a day. This process takes several minutes for an entire state's worth of data, and system response for users will be reduced while the process is running. Currently the system does not contain logic to handle partial updates to an individual facility's information, and errors would result from a single day's data being transmitted in two pieces. Analysis needs to be done to more fully understand how partial data feeds would be sent to ensure that the import processes can be modified to handle the various permutations (full or partial re-transmittal, correction, deletions, additions) of data availability accurately.	1	1	1	2	1

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		USER PRIORITIES (1=higher 4=lower)				4=lower)
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTI	ONALITY CURRENTLY INCLUDED IN ODIN VERSI	ON 2				
Include the ability to handle different identifiers and de-identifiers, with a goal towards standardized de-identifiers and identifiers.	ODIN accepts and stores, but does not process, coded identification information. While it is possible to include a decoding capability, this functionality may not practical from a policies and rules basis. At this time users can see the coded identification information that was transmitted with any particular detail record that they have valid access to, and can then contact the supplying organization to identify the specific individual. More definition of this requirement is required to determine how it might affect the future versions of the system.	3	3	1	2	2
2g. RODS – pharmacy sales information	This functionality is in the Version 2 release of ODIN (using simulated RODS data) which will be previewed on the mid-April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	2	2	4	3	2
Provide the data providers with the same analysis capability for their data as LHJs and DOH have.	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	4	3	1	4	3
Include the ability to perform data extracts for research (with written approval of each LHJ, as some existing data sharing agreements with data providers may explicitly forbid use of data for non-Public Health purposes.)	This functionality is in the Version 2 release of ODIN which will be previewed on the mid- April demonstration CD-ROM's and will be available in the July 1 Version 2 Release	4	3	4	3	3-4

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		USER PRIORITIES (1=higher 4=lower)			4=lower)	
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTIONALITY PARTIA	ALLY DEVELOPED IN ODIN V2ADDITIONAL REQ	UIREM	ENTS	NEED	ED	
1i. Include current functionality used by LHJs as a part of the ODIN toolkit. / USER NOTES: Goal is to avoid referring to multiple, slightly different systems. It will be essential for ODIN tools to be evaluated (especially relative to ESSENCE) prior to their release.	It is believed that ODIN will encompass the requested functionality, but not in an identical manner to the ESSENCE system, however this belief cannot be validated until the V2 system has been reviewed by the stakeholders, and any important deficiencies stacked into the V3 development plan.	1	1	1	4	1-2
1p. Include LHJ-specific analysis capabilities; this would include simple statistics and trend analysis on data. / USER NOTES: Similar to 1e	This functionality is partially developed in V2, but requires interactive dialog with the stakeholders leading to a comprehensive user requirements understanding to be fully implemented	1	1	1	2	1
2d. Lab data both from data providers and commercial laboratories including the feeds from Electronic Laboratory Reporting Systems and aggregator systems such as PHRED	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	1	2	4	3	2
2di. Laboratory reportable conditions	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	1	2	4	3	2
2j. School and business absenteeism data / USER NOTES: Some LHJs will be receiving these data shortly and we want to have the ability to analyze them immediately.	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	2	1	4	4	2

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		US	ER PRIO	RITIES (1	=higher	4=lower)
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTIONALITY PARTIA	ALLY DEVELOPED IN ODIN V2ADDITIONAL REQ	UIREM	ENTS	NEED	ED	
2l. EMS/911 dispatch data / USER NOTES: Many systems currently have these data and it would be helpful if LHJs could analyze these data immediately.	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	3	1	4	4	2
2a. Poison Control Data / USER NOTES: Some LHJs should be receiving these data shortly and we want to have the ability to analyze them immediately.	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	1	1	4	1	1
2e. Communicable Disease case reports	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	2	3	4	2	2-3
2h. BioSense	It is believed that ODIN will encompass most BioSense functionality, but not in an identical manner to the BioSense system, however this belief cannot be validated until the V2 system has been reviewed by the stakeholders, and any important deficiencies stacked into the V3 development plan.	2	3	4	3	2-3
2c. Over the Counter Pharmacy sales information	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	3	2	4	3	3

Report Type Project Name	
Project Charter	ODIN Health Data Surveillance and Analysis Toolkit

		US	ER PRIO	RITIES (1	=higher	4=lower)
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTIONALITY PARTIA	ALLY DEVELOPED IN ODIN V2ADDITIONAL REQ	UIREM	ENTS	NEED	ED	
2dii. Select Laboratory Test Requests	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	3	2	4	3	3
2f. Primary care discharge information	Support for this functionality exists in V2, but it is not implemented for this specific information type yet. More definition of this requirement is required. It is unclear if this information is available from primary care providers in an electronic form. Does this refer to a diagnostic disposition such as an ICD9, or to another code referring to patient disposition (admitted, release, deceased). Need to develop a better definition of the availability and consistency of this data element in the data source community.	1	3	4	1	3
2i. PHIMS reports	This functionality exists in V2. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	2	3	4	2	3
2k. Medical examiner data	The framework to support this functionality exists in V2, but it is not implemented for this specific information type yet. This is a dimension that might be included in V3. Two factors will play into the actual implementation plan. The primary factor will be the success of locating and establishing a relationship with a suitable source for the data. The second would be the relative priority of this specific data feed when considered with the other novel data feeds that are available for implementation.	3	2	4	4	3-4

Report Type Project Name	
Project Charter	ODIN Health Data Surveillance and Analysis Toolkit

		US	ER PRIO	RITIES (1	=higher	4=lower)
ODIN Health Data Surveillance & Analysis Toolkit: User Needs	ODIN Current and Planned Development Status	DOH	SKC	Kitsap	Tac- Pierce	COMBINED PH USER Priority (Est.)
FUNCTIONALITY DEFFE	ERED UNTIL ODIN VERSION 3ADDITIONAL REQU	JIREMI	ENTS I	NEEDE	ED	
1x. Provide tools for ODIN users to facilitate communication with one another to discuss aberrations detected by the system. For example, users will have the ability to flag a signal that requires follow-up or might be of interest to other users, and to post a message next to that item as well as to distribute email to a selection of users who should review that signal.	Development of this functionality has been deferred until Version 3 of ODIN to allow for an interactive dialog with the stakeholders leading to a comprehensive user requirements understanding	2	1	1	1	1
1s. Include automated notifications of statistical anomalies in the data, with an ability to configure the notification by LHJ (this includes who in the LHJ is notified and what constitutes a statistical anomaly). The users will select which algorithms to monitor for notification. Should be provided in the context of DOH "SECURES" communication system. USER NOTES: Must closely monitor the use of automated notifications, at least until the algorithms are completely refined to avoid numerous false alerts.	This requirement is related to requirement 1x. Development of this functionality has been deferred until Version 3 of ODIN to allow for an interactive dialog with the stakeholders leading to a comprehensive user requirements understanding	2	3	1	1	2
ADDITIONAL REQUIREMENTS NEEDED TO DETERMINE FEASIBILITY						
2b. Coded Emergency Department discharge information / USER NOTES: This functionality is currently available in some LHJ systems as well as in ESSENCE, and will be key for pandemic influenza surveillance.	More definition of this requirement is required. Does this refer to a diagnostic disposition such as an ICD9, or to another code referring to patient disposition (admitted, release, deceased). Need to develop a better definition of the availability and consistency of this data element in the data source community.	2	1	1	1	1

end appendix b.

ODIN End User Needs From Charter Process and ODIN status at start of charter process	ODIN Status February 06  np = not present cud = currently under development (i.e., started but not completed)	Notes
Note: Items preceded by 1. = Public Health and Partners' Immediate User Requirements		
Note: Items preceded by 2. = Additional Data Sources for Potential Linkage to the System for Analysis		
NOTE: ROWS ARE IN ORDER OF AVERAGE JURISDICTION PRIORITY		
1a. Provide a WA state regional analysis view (see subitems (1ai) and (1aii)	present	
1aii. LHJs will not have access to other LHJs data analyses.	present	
1c. Include role-based security with roles for hospitals, LHJs and DOH.	present	
<ol> <li>Include security protections such that one hospital cannot see another hospital's data, and one LHJ cannot see another LHJ's data.</li> </ol>	present	
<ol> <li>Include the ability to add additional data sources to the system (e.g., school absenteeism, pharmacy sales, laboratory results) and develop tools for analyzing those data sources.</li> </ol>	present	
<ul><li>1m. Include the capability to perform syndromic statistical analysis by both by hospital location &amp; patient residence.</li></ul>	present	
<ol> <li>Include the ability to download the data using common data formats (e.g., .xls, .txt, .dbf, xml).</li> </ol>	present	
<ol> <li>Include automated capability to continuously evaluate data and promptly address problems with data.</li> </ol>	present	
1ai. DOH and LHJs will be able to see regional analyses; and	cud	
<ol> <li>Provide the hospitals with access to their analyzed data via secure web sites (updated on an automated, daily basis or more frequently if necessary.)</li> </ol>	cud	

1e.	Provide dynamic capability for multiple syndromic coders (including, but not limited to, NYC, RODS, EARS, ESSENCE) along with the ability for individual LHJs to create, modify, and store customized coding algorithms.	cud	
1h.	Include the best and most current chief complaint coders and data analysis algorithms as defined by technical and academic experts in advanced surveillance methods.	cud	Requirements under development
1j.	Include the ability to easily modify, duplicate or update standard syndromic statistical analysis algorithms.	cud	
1k.	Include the capability for LHJ and DOH users to duplicate, add, update, modify syndromic statistical analysis algorithms for event detection analysis.	cud	
11.	Include the capability to maintain an "Unlimited" number of unique syndromic analysis algorithms and syndromic condition coding algorithms.	cud	
10.	Include the ability to evaluate existing data sources, algorithms, and coders concurrently.	cud	Through work with University of Washington
1p.	Include LHJ-specific analysis capabilities; this would include simple statistics and trend analysis on data.	cud	In requirements process
1q.	Provide a single, common look-and-feel user console for the system. All LHJs, DOH and hospital users will use the same tools for performing updates, data and statistical algorithm displays.	present	
2d.	Lab data both from Hospitals and commercial laboratories including the feeds from Electronic Laboratory Reporting Systems and aggregator systems such as PHRED	cud	
	2di. Laboratory reportable conditions	cud	
	2dii. Select Laboratory Test Requests	cud	
1g.	Include the ability to create, upload and maintain the chief complaint coding algorithms by adding, editing, and deleting additional local codes and algorithms dynamically.	cud	
1s.	Include automated notifications of statistical anomalies in the data, with an ability to configure the notification by LHJ (this includes who in the LHJ is notified and what constitutes a statistical anomaly). The users will select which algorithms to monitor for notification, e.g., the ESSENCE algorithm.	cud	
2b.	Coded Emergency Department discharge information	cud	
2g.	RODS – pharmacy sales information	cud	
2c.	Over the Counter Pharmacy sales information	cud	

1n. Include the capability for analyses to be run at preset periods several times per day and on demand so that results can be refreshed if data are received from hospitals at different times throughout the day.	np	Anticipated but no formal requirements created
<ol> <li>Include the ability to perform data extracts for research (with written approval of each LHJ, as some existing data sharing agreements with hospitals may explicitly forbid use of data for non-Public Health purposes.)</li> </ol>	np	Anticipated but no formal requirements created
<ol> <li>Include the ability to handle different identifiers and de-identifiers, with a goal towards standardized de-identifiers and identifiers.</li> </ol>	present	
<ol> <li>Provide the hospitals with the same analysis capability for their data as LHJs and DOH have.</li> </ol>	present	
2e. Communicable Disease case reports	np	Anticipated but no formal requirements created
2f. Primary care discharge information	np	Anticipated but no formal requirements created
2i. PHIMS reports	np	Not anticipated
2j. School and business absenteeism data	np	Anticipated but no formal requirements created
2k. Medical examiner data	np	Anticipated but no formal requirements created
2l. EMS/911 dispatch data	np	Anticipated but no formal requirements created
2a. Poison Control Data	np	Anticipated but no formal requirements created
Include the complete ESSENCE analysis and reporting functionality as a part of the ODIN system.	np	Requirement infeasible due to factors outside developers control

### APPENDIX D

**Puerto Rico Conference Poster** 





# Puget Sound Infectious Disease Tracking System





Peter J Dunbar, MD, ChB, MBA, Ian S Painter, PhD., Linda Lekness RN, MBA Foundation for Health Care Quality, 705 2nd Ave, Suite 703, Seattle WA 98104

### Introduction

The purpose of this project is to investigate the feasibility of implementing a cross-jurisdictional disease surveillance system in the Puget Sound region. The major goals of this project are:

- •To examine the technical feasibility of setting up a shared data-analytic application across a number of jurisdictions
- •To understand the relative utility of data gathered through these techniques for all the involved parties
- •To identify and develop technical and policy approaches to cooperation including the implication of bi-directional data exchange between civilian and military public health surveillance systems.

To answer these questions the project has been split into three parts:

- Policy development process
- Technical system development
- Ongoing research capability development

# Results and Findings

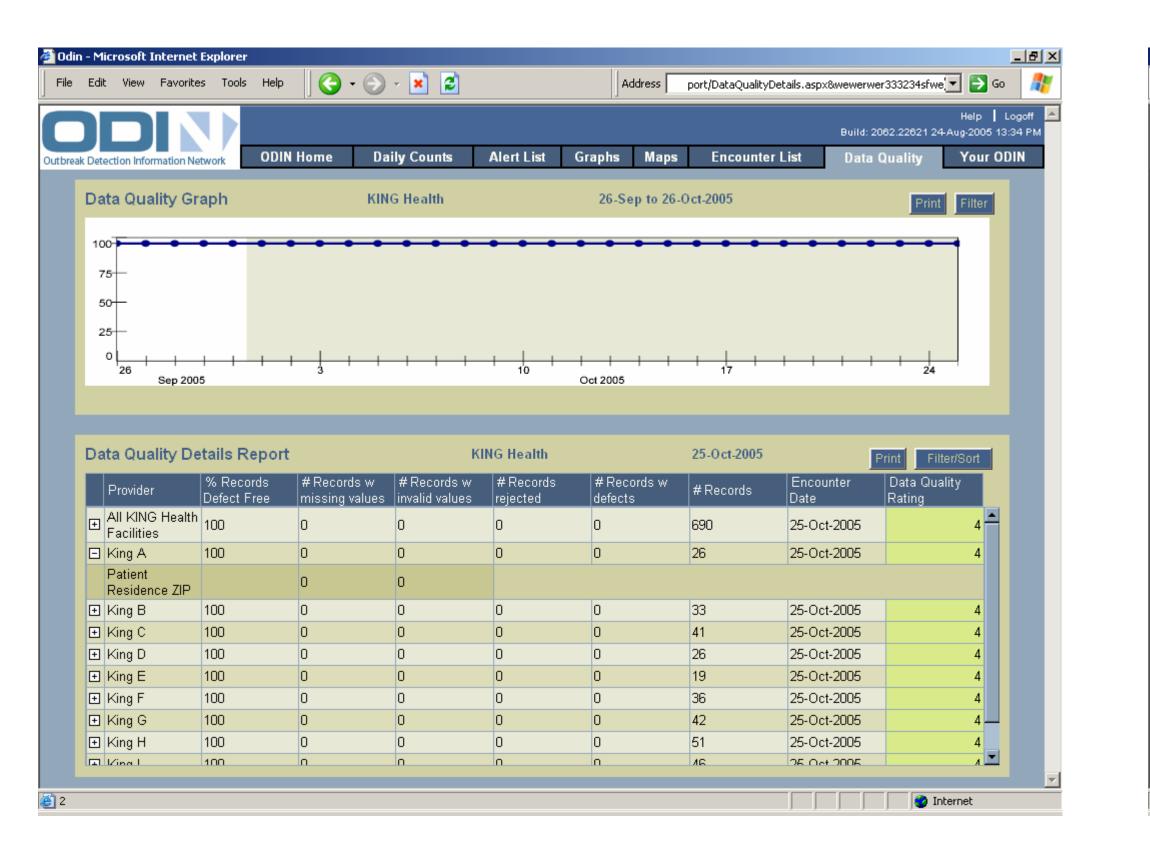
- -The technological challenges were easily addressed by the contractor.

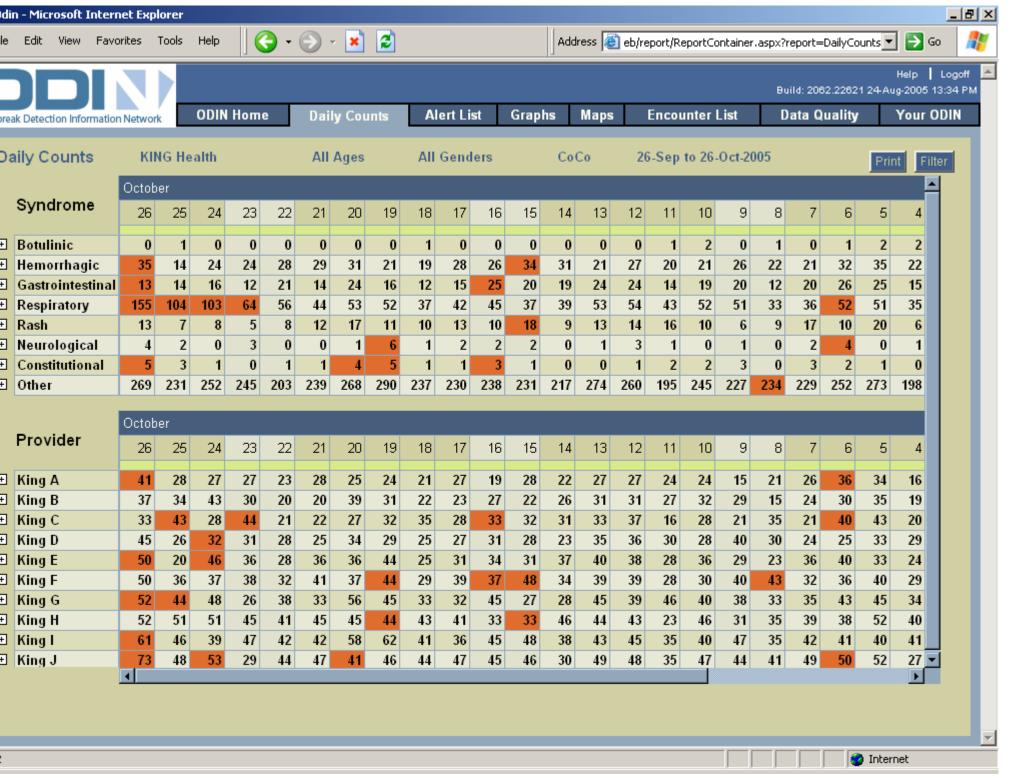
  A prototype application (called ODIN) has been developed. It is being used to demonstrate the technology and as a tool to elicit more detailed requirements.

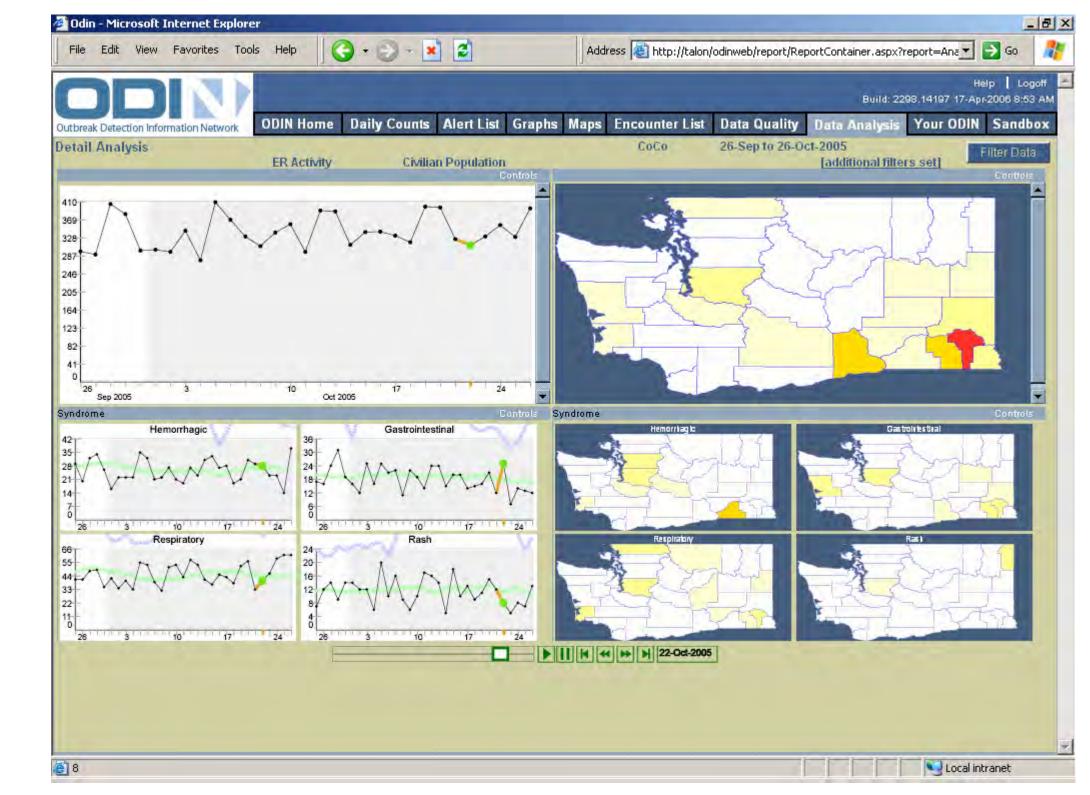
  Design of version II is underway.
- -Substantial challenges exist in integrating the local health jurisdictions (county public health departments) and state department of health into the project. Our initial approach to engage these parties did not meet with success. A revised approach is proving more successful. Publication of the methods used in this approach will be beneficial to other parties outside of the public health agencies which need to work with public health agencies on informatics projects.
- -The research capability component has gone very smoothly, with substantial results. The University of Washington has successfully leveraged expertise developed in this process to obtain a Center of Excellence in Public Health Informatics grant of \$3.8m from the CDC and a training grant from the National Library of Medicine.

# Technical system development

### Prototype version screen shots





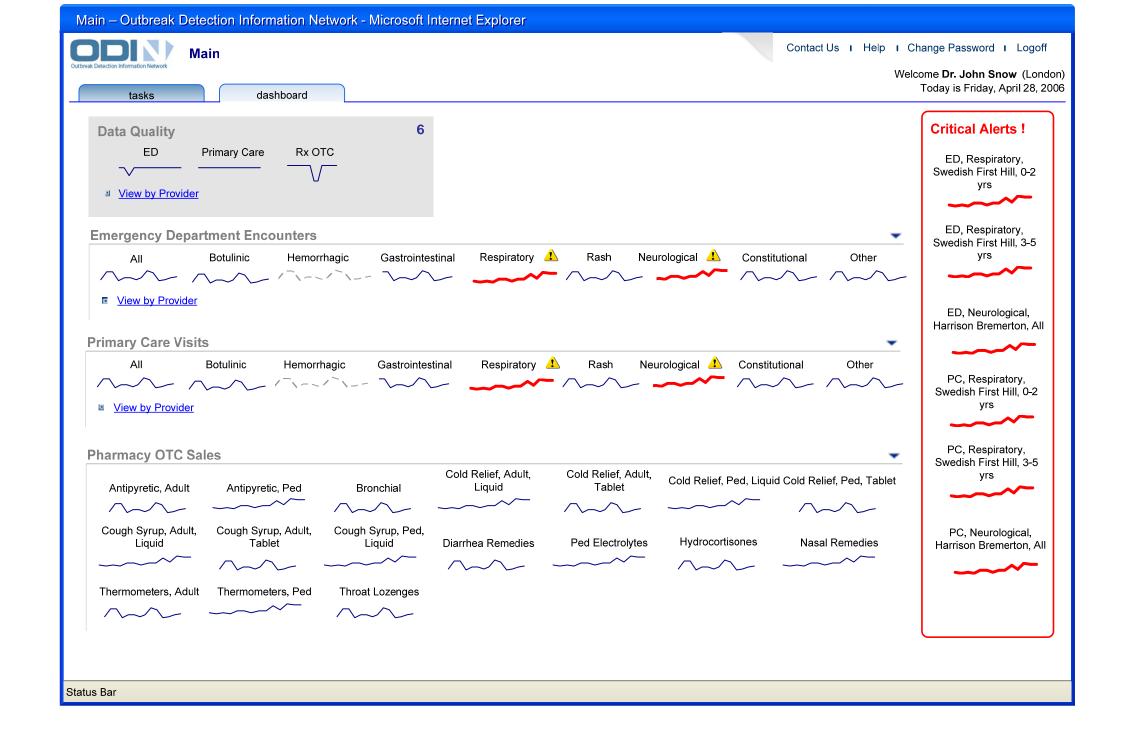


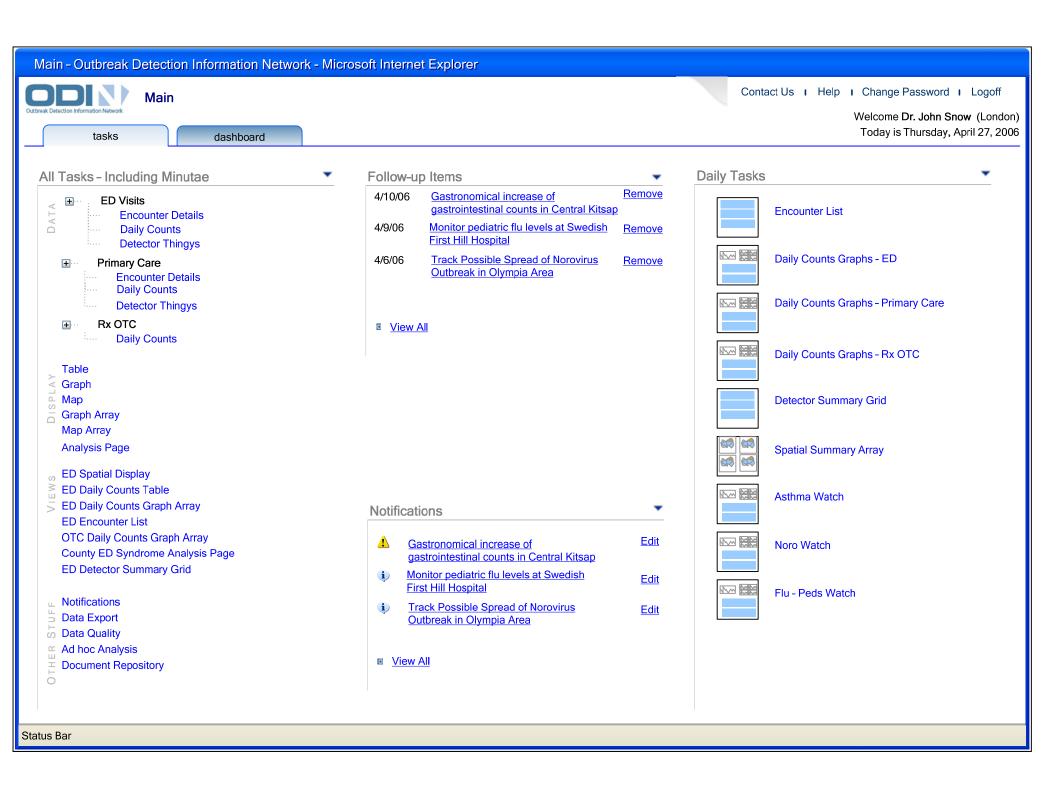
System development was contracted to Paladin Data Systems, a data base and application development company. Technical aspects of the development have proceeded very smoothly, the use of a professional software development organization has proven to be a major factor in the progress to date.

A major issue has been the difficulty in engaging the local public health agencies directly into the development process. This issue has been addressed in the development process as follows:

- By using a flexible application and data base architecture
- -By making use of a surrogate end user with domain expertise to help develop detailed requirements.
- By using the Agile development process, with one month development cycles
- By development of a prototype which is being used to refine the user interface and optimize application workflow.
- •Through use of a large and realistic simulated data set, which simulates all ER visits in the State of Washington over a two year period, and includes a simulated major disease outbreak and simulated data errors.

### Version 2 page layouts (under development)





### Policy development

We have identified several issues that are potential barriers to examining and developing the necessary policies for a shared data system, including:

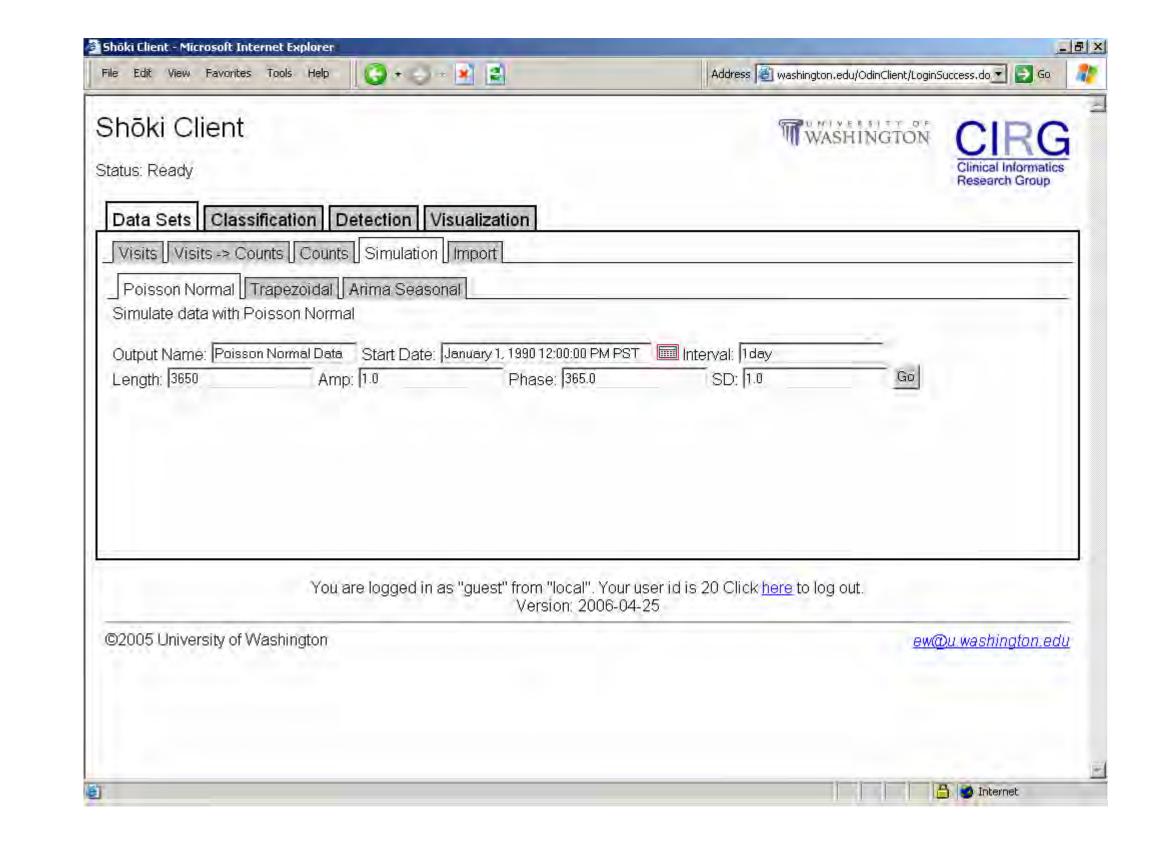
- •jurisdictional issues between the local public health agencies and the state public health agency
- questions about the cost-benefit equation for syndromic surveillance
- overlap with other projects
- data sharing and privacy concerns
- •organizational cultural differences between public health agencies and other groups involved in the process

After exploring several options, the Foundation for Health Care Quality has engaged several local health jurisdictions (Seattle King County Public Health, Kitsap County Health District, Tacoma-Pierce County Health Department and Snohomish Health District) and the Washington State Department of Health in a process to develop a charter that will be used to address policy issues that arise from sharing surveillance data across jurisdictional lines.

The long term goal of this process is to develop a process that can be used to address policy issues for any public health cross jurisdictional information technology project.

# Ongoing research

The University of Washington's Center for Public Health Informatics was contracted to develop methods for public health informatics in areas of use to syndromic surveillance. Among other research activities, the Center is developing an online application to allow public health agencies to analyze the performance of standard syndromic surveillance algorithms on their own data, using an internet services model.



-----Original Message-----

From: Andrew Fallat [mailto:afallat@qualityhealth.org]

Sent: Tuesday, December 23, 2003 2:34 PM
To: 'Ward, Sherry L Dr USAMRMC'

Cc: 'Peter Dunbar (E-mail)'; 'Todd Langton (E-mail)'

Subject: PRO33147 - Puget Sound Infectious Disease Tacking System (PSIDTS)

The purpose of this email is to follow-up on our telephone conversation on Monday, December 22, 2003. We appreciate your observations and believe we have addressed each topic. I am concerned that the memo is longer than anticipated but I concluded that it was better to provide a more thorough record for your review.

### Does PSIDTS still have value to DoD?

PSIDTS has immediate and time sensitive value to Department of Defense (DoD) personnel. We are concerned that benefit may be compromised if the Proposal is delayed and opportunity to work with DoD ESSENCE leadership at Madigan Army Medical Center is lost during DoD's JSIPP implementation. We believe that the (unfunded) work we have accomplished since receiving Patricia Evans, Contracting/Grants Officer's 9/10/03 Recommendation for Funding letter has significantly improved the Proposal's value to the military.

The Military Relevance Statement provided with the Proposal remains sound, without any reservation whatsoever. PSIDTS will develop and evaluate different techniques to acquire data on civilian health populations. In collaboration with cross-jurisdictional public health leaders, this data provides the first <a href="Immediate Benefit">Immediate Benefit</a>: a regional sentinel system. The Long Term benefits remain the same, with the exception of researching additional means of integrating with ESSENCE rather than a web-based system. This improvement addresses a weakness identified and articulated by DoD Programmatic Reviewers in their critique (see next section).

The 9/10/03 Funding letter recommended that a partnership with researchers at the Department of Defense Global Emerging Infections System http://www.geis.ha.osd.mil/. We have accomplished this partnership and have secured GEIS participation on PSIDTS Steering Committee, through LTC Julie Pavlin, Head, Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE) http://www.geis.ha.osd.mil/GEIS/SurveillanceActivities/ESSENCE/ESSENCE.asp.

Through collaboration with Madigan Army Medical Center and ESSENCE we learned that Fort Lewis (the home base for Madigan Army Medical Center) was selected as a JSIPP site. PSIDTS is committed to partnership and value to DoD: therefore it appeared to increase PSIDTS's value to DoD to work within the priorities and interests of DoD as established for Fort Lewis.

http://www.geis.ha.osd.mil/GEIS/SurveillanceActivities/ESSENCE/JSIPPexsum.asp.

Our partnership with GEIS, ESSENCE and Madigan has increased value to DoD. On the other hand, if we fail to move ahead and secure the immediate benefits of a regional sentinel system in the strategically valuable Pacific Northwest (using the collaborative interests of DoD's other major initiative ESSENCE) we may lose a time sensitive opportunity.

### Does the absence of a letter confirming access to data on military subjects merit a delay?

The absence of a letter confirming access to data on military subjects is not unusual at this stage in the Proposal. In fact, it was anticipated that Tasks 1 and 3 would articulate the privacy/security issues prior to securing access. It may be ironic that a Proposal designed to research practices/policies to improve partnership between civilian/DoD may be delayed because it could not secure, in advance, an objective that was scheduled for its end.

Unlike research utilizing the clinical details of specific DoD personnel (and therefore clearly described in a proposal and dependent on access to clinical data on military subjects), PSIDTS relies on access to civilian data which creates a regional, sentinel system available to DoD. This civilian information is valued by DoD, will be integrated into ESSENCE and used by DoD to expand its knowledge of Community-based Infections affecting

DoD personnel. It is the intent and on-going practice of DoD/ESSENCE to share data with civilian authorities; however, before a specific confirmation of access can be solicited, Proposal's Task 1 needs to begin.

Access to data on military subjects is being addressed in accordance with the original Statement of Work. DoD leadership accepts responsibility for releasing access to data and will do so only when the utility to DoD is addressed and security in place to assure mandated confidentiality. Indeed, this work was anticipated in Proposal's Tasks 1c, 1d, 3a, 3c, 3d and 3e (all related to developing standards and policies related to data access).

It was also recognized that PSIDTS may be in partnership with either Madigan or GEIS, or both. (Tasks 3a, 3d) We secured a Letter of Collaboration with Madigan indicating that more specific requests would go to their IRB if and when that request was essential. We consulted with LTC Julie Pavlin who described the ESSENCE approach to access to data on military subjects (see attached Word document entitled "Memo for Sharing), in which citations are provided indicating that it is both authorized and previous practice for DoD to share surveillance data with civilian authorities.



Memo for sharing TMA data.doc

We conclude that a major accomplishment of this Proposal will be to assist civilian communities and DoD learn methods and policies essential to timely and appropriate sharing of surveillance information. We believe that DoD's ESSENCE project is leading the way and we intend to work with ESSENCE through Task 1 to bring in other military approvals as necessary.

We conclude it is futile (and perhaps a detriment to developing future infectious surveillance partnerships with DoD) to attempt to secure detailed letters of assurance without first accomplishing the work described and funded in Task 1.

### Should the Statement of Work be amended and resubmitted?

The Statement of Work remains an accurate description of our Proposal. We will broaden input methods into the Surveillance system, in recognition of comments made by Programmatic Reviewers and other DoD leaders in ESSENCE.

The Statement of Work describes five major Tasks, with 16 sub-tasks. Task 2 identifies developing a web-based case reporting system. The four Task 2 sub-tasks are generic to case reporting and not dependent on web-based reporting. Collaboration with DoD personnel within ESSENCE indicates that other input systems are preferred. These comments are consistent with weaknesses identified in the Programmatic Reviewer's comments (p.7): "The proposal may overestimate the workability of the Web-based tool for providers to use". And again: "One concern relates to...the time required to input data into the automated data collection system". The four sub-tasks under Task 2 remain relevant except that they will be applied to other collection methods consistent with ESSENCE. Stated differently, all 16 of the sub-tasks are relevant and will be performed.

We also believe that bi-directional exchange of information will occur with DoD, in accordance with the stated goal of ESSENCE and the established practice of DoD related to Infectious Surveillance. We see no change to Statement of Work in that arena.

I have neither expertise nor experience on which to base a conclusion regarding the necessity of an amendment. It seems to be administratively complex, however, to resubmit a new Statement of Work because of a heading change when all the sub-tasks remain the same. We believe the input process was improved by replacing a technique that was described as a "weakness" by Programmatic Reviewers with another process preferred by DoD partners we were encouraged by DoD to invite to the Proposal.

### Is "cost-reimbursed" grant acceptable to the Foundation?

Yes, a cost-reimbursement grant award is acceptable to the Foundation. The Foundation does not have working capital sufficient to make other than nominal advances to staff and vendors. Likewise, the Foundation cannot risk incurring expenses without assurance that they will be reimbursed. As long as "cost-reimbursed" permits

both a reasonable amount of working capital and staffing adequate to handle Foundation requests (with quick turn around) for assurance about specific potential expenses, then "cost-reimbursed" is acceptable.

Thank you for the opportunity to respond to your observations. We appreciate your consideration of funding decisions essential to our beginning work on PSIDTS. We anticipate your call to Todd Langton on December 30.

Andrew Fallat President/CEO Foundation for Health Care Quality Seattle, WA

### APPENDIX F

Agreement between FHCQ and DOH – to insert

### AGREEMENT

### BETWEEN FOUNDATION FOR HEALTH CARE QUALITY (FHQ) STATE OF WASHINGTON DEPARTMENT OF HEALTH (DOH)

PURPOSE: The purpose of this contract is to contrast two syndromic surveillance software applications in their ability to gather process and provide disease incidence data on which to base public health response decisions.

TERM: Subject to its other provisions, the period of performance under this contract shall be from December 1, 2006 through December 31, 2007 unless sooner terminated as provided herein.

STATEMENT OF WORK: DOH shall provide the goods and services as described in EXHIBIT A, STATEMENT OF WORK, attached hereto and incorporated herein.

**CONSIDERATION:** The maximum consideration available under this contract is \$ payable in accordance with EXHIBIT A, attached hereto and incorporated herein.

SOURCE OF FUNDS: FEDERAL: \$ STATE: \$0

OTHER: \$0

TOTAL: \$2

Federal funds disbursed through this contract were received by FHQ through OMB Catalogue of Federal Domestic Assistance Number: 12.420. DOH agrees to comply with applicable rules and regulations associated with these federal funds.

**INVOICES AND PAYMENT:** Department of Health will bill the Foundation for Health Care Quality on a quarterly basis, and, within 45 days of the end of the quarter. The invoice for the last quarter of 2007 will be billed no later than December 31, and will be due to Department of Health by January 15, 2008.

FHQ will make payment to DOH within 30 days upon receipt of properly executed invoice vouchers.

PRECEDENCE: In the event of conflict or inconsistency, the following order of precedence shall apply: (1) federal law and regulation, (2) state law and regulation, (3) this agreement.

UNDERSTANDING: This contract including referenced exhibits, attachments and documents included by reference contains all the terms and conditions agreed upon by the parties. No other understandings, oral or otherwise, regarding the subject matter of this contract shall exist or bind any of the parties hereto.

The parties to this agreement agree to abide by and fully comply with the provisions set forth herein.

DOH CONTRACTING OFFICER SIGNATURE	DATE
130 Bl	11/29/06
FOUNDATION FOR HEALTH CARE QUALITY SIGNATURE	DATE

### GENERAL CONDITIONS

- 1. AMENDMENTS This contract may be amended by mutual written agreement of the parties. Such amendments shall not be binding unless they are in writing and signed by personnel authorized to bind each of the parties.
- 2. CONFIDENTIALITY/SAFEGUARDING OF INFORMATION AND PRIVACY The use or disclosure by any party of any information concerning a client obtained in providing service under this agreement shall be subject to Chapter 42.56 RCW and Chapter 70.02 RCW, as well as any other applicable federal and state statutes and regulations. Personal information collected, used or acquired in connection with this contract shall be used solely for the purposes of this contract and other public purposes.
- 3. FEDERAL CERTIFICATIONS AND ASSURANCES AND DEBARMENT AND SUSPENSION FHQ and DOH agree that all activities pursuant to this Agreement will be in accordance with applicable current or future federal, state, and local laws, rules, and regulations. DOH certifies that it is not debarred, suspended, or otherwise excluded from or ineligible for, participation in Federal or State government contracts. DOH further certifies that it will not contract with a Subcontractor that is so debarred or suspended.
- 4. **DISPUTES** The parties shall use their best, good faith efforts to cooperatively resolve disputes and problems that arise in connection with this Contract. Both parties will continue without delay to carry out their respective responsibilities under this contract while attempting to resolve the dispute under this section. When a genuine dispute arises between the FHQ and DOH regarding the terms of this agreement or the responsibilities imposed herein which cannot be resolved at the project management level, either party may submit a request for a dispute resolution.
  - This dispute resolution process constitutes the sole administrative remedy available under this contract. The parties agree that this resolution process shall precede any action in a judicial and quasi-judicial tribunal.
- 5. GOVERNING LAW This contract shall be governed by the laws of the State of Washington and applicable federal laws and regulations. The Venue of any legal action or suit concerning this agreement shall be the Thurston County Superior Court and all actions or suits thereon shall be brought therein.
- 6. HOLD HARMLESS Each party shall defend, protect, and hold harmless the other party from and against all claims, suits, and/or actions arising from and negligent or intentional act or omission of that party's employees, agents, and/or authorized subcontractor(s) while performing this contract. Claims shall include, but not be limited to, assertions that the use or transfer of any software, book, document, report, film, tape, or sound reproduction or material of any kind, delivered hereunder, constitutes an infringement of any copyright, patent, trademark, trade name, or otherwise results in an unfair trade practice.
- 7. LIMITATION OF AUTHORITY Alterations, modifications, or waivers of any clause or condition of this contract is effective or binding only if in writing and signed by duly authorized representatives of both parties.
- 8. SUBCONTRACTING DOH is responsible for ensuring performance of its subcontractors and that all terms, conditions, assurances and certifications set forth in this agreement are carried forward to any subcontracts.
- 9. **TERMINATION** Except as otherwise provided in this contract, either party may, by THIRTY (30) calendar days written notice, beginning on the second day after the mailing, terminate this contract in whole or in part when it is in the best interests of that party.

### **HIPPA**

### **Status of Legal Issues**

Analysis and recommendation of HIPAA application provided by John R. Christiansen, Christiansen IT Law, a law firm specializing in technology related services

### Legal Issues Resolved to Date:

Issue	Discussion
Scope of data available for contribution to ODIN	HIPAA prohibits disclosure of Protected Health Information for most public health purposes, unless individual authorization is obtained. Obtaining such authorization may be difficult or sometimes impossible. However, HIPAA expressly does permit disclosure of "Limited Data Sets" for public health purposes without such authorization. Limited Data Sets appear to provide sufficient information for ODIN purposes.
Authority to use data processing vendors to provide ODIN data	Many hospitals rely upon data processing services vendors to store and manage their Protected Health Information. However, HIPAA requires Covered Entities (including hospitals) to limit the uses and disclosures such vendors may make of their Protected Health Information. Model contract provisions authorizing vendors to create and disclose Limited Data Sets on behalf of hospitals for public health purposes, including ODIN, have been developed and found acceptable to both a major data processing services vendor and a number of hospitals.

### Legal Issues to be Resolved

Issue	Discussion
Specify public health reporting laws supporting disclosure of ODIN data	HIPAA authorizes disclosure of Protected Health Information for public health purposes but requires that those exceptions be specified. Public health laws requiring or permitting disclosure may be either federal or state. There may be a number of alternative public health legal bases for ODIN disclosures; the specific legal bases therefore should be specified.
Specify public health authority of ODIN data receivers to obtain Protected	HIPAA requires legal authority for entities to receive Protected Health Information from Covered Entities for public health (and other) purposes. Public health authority is usually but not necessarily vested in governmental authorities (federal, state or local). The specific authority for the ODIN data receivers to obtain such

Health Information	information should be specified, or if none currently exists should be developed.
Establish security governance for ODIN participation	In order to provide assurance to ODIN participating organizations that they will be able to maintain HIPAA security compliance, a security governance committee should be established which develops policies, procedures and technical guidance for ODIN participation.
Publish legal interpretation supporting ODIN participation	In order to encourage ODIN participation, a legal opinion (perhaps in the form of a white paper) should be published which summarizes the legal bases for participation in compliance with HIPAA and Washington state law.